UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON DIVISION

BRISTOL-MYERS SQUIBB COMPANY,

Plaintiff,

-vs-

APOTEX, INC. and APOTEX, CORP.,

Defendants.

CIVIL ACTION NUMBER:
3:10-cv-05810-MLC-LHG

BRISTOL-MYERS SQUIBB COMPANY,

Plaintiff,

-vs-

APOTEX, INC. and APOTEX, CORP.,

Defendants.

CIVIL ACTION NUMBER:
3:10-cv-06918-MLC-LHG

MARKMAN HEARING

Clarkson S. Fisher United States Courthouse
402 East State Street
Trenton, New Jersey 08608
October 2, 2012
10:05 a.m.

B E F O R E: THE HONORABLE MARY L. COOPER
UNITED STATES DISTRICT JUDGE

Certified as true and correct as required by Title 28, U.S.C., Section 753./S/ Regina A. Berenato-Tell, CCR, CRR, RMR

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INDEX

TRENTON, NEW JERSEY TUESDAY, OCTOBER 2, 2012 10:05 A.M.

(Call to order of the Court.)

THE COURT: Good morning, everyone. Welcome back.

Welcome to our court reporter. This is her first appearance in our Court.

I'll take your appearances now.

MS. BEN-AMI: Good morning, Your Honor. Leora Ben-Ami from Kirkwood for Bristol-Myers.

MS. WACKER: Jeanna Wacker, also from Kirkland.

MS. GANNON: Christine Gannon from Connell Foley.

MS. FRENCH-BROWN: Wanda French-Brown from Kirkland.

MR. HSING: Benjamin Hsing of Kaye Scholer for Bristol-Myers.

MS. MAZZOCHI: And Deanne Mazzochi.

MR. SHANNON: Luke Shannon, Rakoczy, Molino, for Apotex defendants.

MR. SOOS: Jeffrey Soos from Saiber, and my colleague Geri Albin.

MS. ALBIN: Good morning.

THE COURT: Okay. Fine. Thank you.

Please go right ahead.

MS. BEN-AMI: Good morning, Your Honor.

I spoke with counsel for Apotex briefly, and we thought that the best way to do this today would be to do all the terms relating to the X-ray diffraction patterns instead of so

related and then switch to Apotex and do the...

THE COURT REPORTER: Can you please speak up?

MS. BEN-AMI: Surely, I will.

Does Your Honor have the binder from last time?

THE COURT: I do.

MS. BEN-AMI: So then I'm going to start at 104.

And as Your Honor knows, we had started on the '725 Patent last time we were together, and now we're going to talk really about the testing issues.

So, this claim term is in Claim 1, and it says, "which is characterized by an X-ray powder diffraction pattern substantially in accordance with that shown in Figure 1." And, Your Honor, on Slide 104 will see Figure 1.

THE COURT: Thank you.

MS. BEN-AMI: So, if we go to the next slide, which is 105, we have for Your Honor the various positions of the parties. And you can see that there are a few issues with Apotex's construction that we look at and see as troubling.

Apotex says that the product must match. And you will see that the claim says, "substantially in accordance." So, that's one point of contention.

And the other point that we can see right off the bat is that it says, "must do so in such a way so as to uniquely identify the referenced crystalline monohydrate of the compound of formula (IV)."

And our position very generally is that that's not the way the claim is written. The claim is written, if we look at Claim 1 -- which Your Honor has with the patent -- is that it says, "it is a crystalline monohydrate of the compound of the formula." And then it says, "which is characterized by this X-ray diffraction pattern." It doesn't say an unknown compound, which is characterized by this pattern. It says you know it has got to be a crystalline monohydrate of that formula, and it has got to be characterized by that pattern or substantially in accordance with that pattern.

So, we can go to 107, please.

And, so, we don't think there's really all that much construction that needs to be done to this claim.

THE COURT: Going back just to your prior slide -- and I'll try not to interrupt much today.

MS. BEN-AMI: That will be fine.

THE COURT: I won't interrupt much today.

MS. BEN-AMI: It is your courtroom, Your Honor.

THE COURT: But I do see that Apotex in their construction has reproduced the chemical drawing that you see in Claim 1 of the '725 Patent.

MS. BEN-AMI: Right.

THE COURT: So, you don't disagree with each other that the chemical drawing --

MS. BEN-AMI: That's correct.

THE COURT: -- is part of Claim 1.

MS. BEN-AMI: That's right. It is. So -- that's right. It is the crystalline monohydrate of the compound of that formula as drawn -- all right -- and then it says, "which is characterized by this test in effect."

So, if we go to 107...

THE COURT: Go ahead.

MS. BEN-AMI: Your Honor has Apotex's, you know, slides, as well, and since we were here together before I have looked at them. And what Apotex is really arguing is indefiniteness, rather than claim construction due to the use of the word "substantially." And it cites to a case of Datamize, but the language in that case --

THE COURT: Can you just, please, spell that one for us?

MS. BEN-AMI: Datamize?

THE COURT: Yes.

MS. BEN-AMI: As I've written it down, it is Datamize, D-A-T-A-M-I-Z-E, versus Plumtree Software.

THE COURT: Okay.

MS. BEN-AMI: So that case was about the language "aesthetically pleasing." And, so, you know, the Court, I think, even used the term "beauty is in the eyes of the beholder," and, so, "aesthetically pleasing" was something that the Court said there's no written description in the

patent to tell you how to define that, and, so, it is completely subjective.

In contrast here, we have a specification that talks about how you're supposed to consider the X-ray diffraction pattern.

And, first of all, as I guess the Court is aware, the use of "substantially" in patent law is very common. But if we look here at the patent -- and that is on the slide -- it shows you in Column 41 and Column 42 the relevant language. It says, "one of ordinary skill in the art will appreciate that an X-ray diffraction pattern may be obtained with a measurement error that is dependent upon the measurement conditions employed." This is something scientists wouldn't know. And, so, it is telling you what people know who do these tests. And it says, "in particular, it is generally known that intensity in an X-ray diffraction pattern may fluctuate, depending upon measurement conditions employed. It should be further understood that relative intensities may also vary depending upon experimental conditions, and, accordingly, the exact order of intensity should not be taken into account."

So, it is making you say -- it is specifically saying when we say "substantially in accordance," you should not be taking the order of intensities into account. And then it goes further -- and I won't read to you the entire language

that we put out here because you will have it -- but then it goes through and it explains the process, and then it says, "any crystal forms that provide X-ray diffraction patterns substantially identical to those disclosed in the accompanying figures fall within the scope of the present invention." And that this is something that people skilled in the art are trained to do, basically.

So, you know, the Federal Circuit has said when you have the language "substantially" look to the specifications and see if it gives you guidance, and here the specification is quite clear that it is telling you how to deal with "substantially," and it uses that language.

So, I think that where we are is "substantially" has a meaning in the law, and there's a meaning in the specifications, so it is -- basically, it should be relatively straightforward.

Can I have 108, please?

And this is a quote from Apotex's expert. And he says, you know, he understands "substantially in accordance" to mean matches well. Okay. Which seems to make sense.

And then if we go to 109, what we're seeing in the patent is the observed pattern and the simulated pattern. And you will see that they are -- the intensities of the peaks might be slightly different and things of that nature, and he is saying, "Yes, I can say that those two are 'substantially

in accordance.'"

THE COURT: I see.

MS. BEN-AMI: So this is a field. There are real experts in this field. And this is what they do. They look at these patterns.

So, 110, please.

There's also agreement that there are inherent errors in these measurements. There are inherent errors in any measurement that you ever do under any testing procedure. And this is Apotex's expert drawing a picture saying that he would say they have the same crystal material, even though they have different intensities in the peaks.

If we go to 111, this is a statement from the testimony of an expert for Apotex in a different case, again, explaining what is in the specification here that there can be a change in intensity because all the crystals may not be lined up the same way.

And in the next slide, 112, we don't have to go through this in detail, but these are just a bunch of cases where other courts have looked at the issue.

And in 113 -- again, we don't have to go through this -- cases where the Federal Circuit and the courts have talked about "substantially."

So if we go to 114, I think this is an important point. Apotex is, basically, saying that it is as if you take a

sample that is unknown -- in chemistry they give you a jar of something, and they say, Here is an unknown. We don't know what is in it. Figure out what it is. Right? And then that, you know, it must match exactly because that's the only way you know what it is. But that's not what the claim says. The claim just says, What features do you need to infringe? You need to have the crystalline monohydrate. It has to be of that compound as defined, and it has to be characterized by the pattern "substantially in accordance."

So, you know, our very basic position on this whole area of testing is we should follow the words of the claim, and we shouldn't read limitations into the claim that aren't there.

If we go on to 115, you'll see in Claim 3 of the '725 Patent it now gets down to even more defined terms that we really don't have to go into a great deal of. The Cu part is -- tells you how the measurements are being done and the temperature. And then it says, "comprising four or more 2 theta values selected from a group consisting of," and then "consisting of" has numbers, and it has plus or minus .2.

THE COURT: Now we're in Claim 3?

MS. BEN-AMI: We are now in Claim 3.

THE COURT: And is it fine that you just keep going with this for a while before we pick up the other set?

MS. BEN-AMI: We had agreed that we'll go through all

the things relating to the X-ray pattern, and then Apotex will go, and then we'll go to the other tests, so that we can get everything done at once.

THE COURT: Fine. I'm with you.

MS. BEN-AMI: If we look at 116, basically, our position is it says what it says. The claim says what it says. And if you look at Apotex's position, again, they're putting in that it must uniquely identify -- it says, "the term '2 theta values' is vague and indefinite," which is not really a claim construction issue. If the Court can construe the claims, even if it is difficult to construe the claims, there shouldn't be a problem, and 2 theta values are well known in the art. "Selected from a group consisting of" is Markush language, but in the context of the claims it is vague and indefinite.

Our position is it is not vague and indefinite at all. You can read it. It says "comprising four or more 2 theta values selected from the group consisting of." And it has a bunch of numbers. And the error rate -- the error bars of plus or minus .2 is written in the claim. So, this is -- you know, this is claim construction right now, and we think the claim terms are what they are.

Can we have 118, please?

This is the language in the specification, which -- from which this claim arises or is supported in part.

And 119, please?

I think it is interesting that Apotex's expert did not opine on Claim 3, but they said that when we look at this -- this is really a summary of pretty much what I mentioned to you before.

THE COURT: Can you just address your second subsidiary bullet point, "the process conditions in this claim." I can't even read these Greek letters, but there is in the claim in the parenthetical some testing conditions set forth, right?

MS. BEN-AMI: The testing conditions that are set forth are the testing conditions that should be used, right? So...

THE COURT: Well, then your bullet point two here says that in your view "Apotex's proposed construction improperly limits the crystalline monohydrate to the process conditions set forth in the patent." What do you mean?

MS. BEN-AMI: The crystalline monohydrate is a separate claim term --

THE COURT: Yes. Oh, yes.

MS. BEN-AMI: -- so the crystalline monohydrate -- to prove infringement we will have to show that they have the crystalline monohydrate of that formula, right?

THE COURT: Hang on. I think I already understand what you're saying.

MS. BEN-AMI: Okay. Okay.

THE COURT: This second bullet point does not refer to the lab testing conditions that you have in the parenthetical in Claim 3 here.

MS. BEN-AMI: Right. Right. Right. So if we go to 120 -- and, again, I think we can go through this quickly because the claim says, "plus or minus .2." And Apotex points to a different case where the courts said that in a specification where it didn't say what the standard error was, and they said it should be .1. Well, it really doesn't matter what that case says because this case says, "plus or minus .2" in the claim itself. So, there's nothing to construe.

And I'll skip the Apotex -- the Abbott case.

And then I'll go to 122. And I believe this goes to claim -- I have lost the claim. The Claim 5?

MS. WACKER: Yes.

MS. BEN-AMI: Claim 5. And, again, our position is if we go to 124 that this is a bunch of numbers and figures, and this is what people who do these tests do. And we believe that it is the plain meaning. There's nothing to construe here.

Apotex's position is that the term is indefinite. And it says what it says. I don't see any construction issue here really, Your Honor. I think it is just the --

THE COURT: Okay. And you can reply if there's

something that you need to respond to.

MS. BEN-AMI: Okay. And that is it for the X-ray part.

MS. MAZZOCHI: Good morning, Your Honor.

THE COURT: Good morning, Ms. Mazzochi.

MS. MAZZOCHI: Because we had a thick binder we weren't sure you were going to be bringing them back, and because last time we were kind of hoping we wouldn't have to discuss this indefiniteness issues, so we have got a fresh binder for you, if that's okay.

THE COURT: Okay.

MS. MAZZOCHI: So, Your Honor, if I may, we can actually start by jumping to Slide Number 5 because I think it is going to be important to explain why it is we think that these claims, notwithstanding what they say on their face, have some problems.

Now, the typical reason why you use X-ray powder diffraction testing is because in theory they're supposed to give a unique fingerprint that is going to be associated with a certain crystal type and a particular type of crystal lattice.

The problem that we have here is that within the '725 Patent itself they have identified multiple crystal forms besides the monohydrate. So, when you start looking more closely at some of the features that have been associated with

these other crystal forms you realize that there isn't necessarily a clear-cut distinction between the different crystal forms to the degree that counsel would like to give the impression on.

So, if we can take a look first at Slide Number 6, one thing I do want to make clear is that if you're looking at an X-ray powder diffraction pattern, that alone isn't going to tell you you do have a monohydrate or you don't have a monohydrate. It is not as though, for example, you can say if I see a peak at 18 I know there's water there.

In fact, their expert admitted that, yes, just from an X-ray powder diffraction pattern you can't tell whether it is a monohydrate, or an anhydrate, or some other type of a crystal form. What you need to have then is a validated reference standard that's been fully characterized then maybe you can make a comparison and analogize that, well, since this PXRD pattern of an unknown sample looks like a PXRD pattern for an established, known, fully characterized sample, if they match, then you can say -- then you can reasonably say, Okay, I think this crystal is the same crystal form. But that's not necessarily the case, and, in fact --

THE COURT: Well, what is X-ray powder diffraction testing supposed to be telling you?

MS. MAZZOCHI: And, actually, if you jump to Slide Number 8, because intuitively it is a hard concept to grasp;

what is it that actually gives rise to the peaks? It requires the application of Bragg's Law and a bunch of mathematical equations, which I won't get into, but what we can think about conceptually -- and this is the way in which I can get my head around it -- all of these pictures here in Slide Number 8 would be considered to be different unit cells.

So, you know, the one on the upper left is a hexagon shape. The one on the lower right is a rectangular shape. These, obviously, are simplified because of the three-dimensional space.

THE COURT: Are these all crystal forms, though, that you're showing here?

MS. MAZZOCHI: Yes, exactly. All different crystal forms -- because the way in which you define a unit cell is based on its geometric shape. And there's about 200 or so different geometric shapes that have been established thus far for crystals that have been grown in nature. So, what the X-ray powder diffractogram is really measuring when it is looking at a peak is what is the distance it took for me to jump from one spot in the unit crystal cell and then jump over to the next spot within the unit crystal cell that's in an identical position in three-dimensional space.

THE COURT: So, the same location in the adjacent cell?

MS. MAZZOCHI: In the adjacent cell, exactly. So,

depending on the length in which it is going, the nature of the space group, the -- you know, the distance between one atom to the next, those are all things that are going to give rise to peaks in the X-ray diffraction pattern as you churn, you know, the detective measures -- I'm sorry, the detective levels of the diffracted X-rays through the mathematical equations.

THE COURT: Churn the detected measures, yes.

MS. MAZZOCHI: Yes. You'll have the X-rays. They hit the powder sample. And the X-rays, as they go through the X-ray units -- as they go through a unit cell, for example, maybe they hit an atom in one location in three-dimensional space, maybe an X-ray can penetrate deeper and go to a different atom in three-dimensional space. And then as it hits an atom it scatters off in a certain direction. Sort of like if you were to bounce a ball on the ground at different angles it will bounce in different directions.

So, conceptually, you wind up doing the same thing with the X-rays. But then when it comes to translating those diffraction patterns into peaks in a powder X-ray diffraction pattern that's what applies -- requires the mathematical operation of Bragg's Law and converting the angles into intramolecular and intraunit cell distances. But, of course, the reason you get these differences in X-rays when you have different unit cells, for example, that's why you do see

differences in the X-ray powder diffraction peaks. But by the same token -- you know, a typical X-ray powder diffraction pattern of organic molecules goes from a range of about 4 to 40 degrees 2 theta. So, of all the hundreds of thousands of compounds and crystal forms that are out there, when you run the PXRD pattern, they're going to have peaks within that very narrow range.

Well, one of the reasons why you get peaks showing up in all these different locations is because it is a measure of intraunit cell distances that ultimately winds up showing up as the peak. So if I could --

THE COURT: Intra? Of intraunit --

MS. MAZZOCHI: Intra.

THE COURT: I thought so. Slow down.

MS. MAZZOCHI: Thank you.

THE COURT: Thank you.

MS. MAZZOCHI: So if we can look, for example, at Slide Number 7, this -- and let's try to blow up where some of these red lines are. One of the reasons why we have got some concerns about them saying, Oh, you know, well, a person of ordinary skill can look at some of these --

THE COURT: Hold on just a minute, please. I have to make a note.

MS. MAZZOCHI: Sure. So, let's look, for example, at this spot here, which is at 26. You can see there's a peak

here in the Figure 1 pattern, right, which is where this red line is. So, there's a peak in the X-ray diffraction pattern that goes up and comes back down.

Now, if we look again at Figure 4, and -- I'm sorry, Figure 3 -- which is for a butanol solvate -- so completely different crystal form. When we look at 26 we see, again, there's another peak there. So, the sheer fact that you see some peaks in the X-ray powder diffraction pattern it doesn't mean that every polymorph has a completely unique set of peaks. It is quite often the case, particularly when you're looking at polymorphs of the same drug compound, that you will, in fact, have peaks that are in similar, if not identical positions, in the X-ray powder diffraction pattern. So, when we start going through then -- let's go to -- let's go ahead and look at the slide as a whole.

So, when we start looking then at some of the ranges that their expert wants to give some of the peaks --

THE COURT: Now you're on Slide 7?

MS. MAZZOCHI: Yes. Still on Slide 7 at the very bottom. Dr. Atwood, their expert, has actually admitted that, yeah, if you look at some of the peaks that are identified either in the PXRD powder patterns or in the specification for some of these different polymorphs that particularly when you start applying the ranges that the plaintiffs want to give some of these peaks in terms of plus or minus .2, for example,

you wind up getting peaks that when you were to try to account, for example, for measurement errors they're going to be overlapping. And we can see this, again, actually if -- I have gone through all the different figures. If we look at Slide Number 9, for example --

THE COURT: But you're taking -- you're taking segments of the printout. You're looking at one small chunk of your linear line --

MS. MAZZOCHI: Exactly. And --

THE COURT: -- and comparing that chunk with a different substance.

MS. MAZZOCHI: Oh, I completely agree with you that if you, for example, visually look at Figure 1 of the '725 Patent for the monohydrate and Figure 3 of the '725 Patent, which is a different crystal form, just visually looking at them you can tell these X-ray powder diffraction patterns, they don't match. But they're trying to say, Well, no, we're allowed to get away from making a match. We're allowed to have some areas where the patterns visually look different based on measurement error and based on a peak moving this way, a peak moving that way, a peak getting bigger, a peak going smaller.

Well, the problem then is what standard are you really going to apply to say these are actually substantially similar, and where do you cross the line to say, No, I can

look at these and know that they're different.

So, that's really where we have a fundamental problem with, you know, what we consider to be a very vague and nebulous standard of substantially in accordance with Figure 1. And I don't need to run through all of these, Your Honor, but what we have done is in Slides 9, 10, and 11, as well, we have drawn in some of the lines that show where you get some, you know, peaks that are showing up in some locations that, you know, maybe one expert says they're closed. Maybe one expert says they're far away. Maybe one expert says it depends on how they were measured. So, then it becomes a question of affirmatively how does the person of ordinary skill in the art decide is this the same, or is it different?

Now, one of the figures that counsel brought up -- let's jump to Slide Number 16 -- was the '725 Patent Claim 1.

Now, Dr. Desiraju was asked the question: "Are these two patterns identical?" And he said, "No, they're actually not identical."

THE COURT: You're comparing Claim 1?

MS. MAZZOCHI: Within Figure 1 itself it has got two X-ray diffraction patterns.

THE COURT: Fine.

MS. MAZZOCHI: So the top one is one that was actually measured, and then the bottom one is one that was -- that they call a "simulated X-ray diffraction pattern."

So, in this particular one if we look, for example, at this region -- this is the one that Dr. Desiraju was testifying about -- he said, Well, if I look in the observed pattern, you know, this is really sort of -- let's call it two peaks in this location, and then there's one right here. But then when we look on the bottom, see there's three, one, two, three?

THE COURT: You're in the column between Line 24 and 26?

MS. MAZZOCHI: Exactly. So, you know -- so here we have a clear difference where he says, No, you can look at those visually and say they're not identical. But then do you turn around and say, All right, are these the same? He said, Well, you know -- and this was the quote that they brought up, they said, Well, you know, can you say that the simulated pattern -- you know, how good of a -- do you say it is substantially in accordance with? He says, Well, I would say that if we talk about that as a qualitative term, is it substantially in accordance, yeah, but that's just -- you know, that's one difference. Are you still substantially in accordance if you have two differences? Three differences? Four differences? Does it matter where the peak appears? Does it matter if it is one versus two peaks? Or, you know, in different locations?

And that's why, you know, I think that ultimately --

you can jump to the next slide -- you know, because we have a situation here for Dasatinib where you have different lattice structures. I'm sorry, jump to the next one.

So, you know, so here we have a situation where you have different lattice structures that are producing not just the occasional peak, but many peaks in the same or similar -- you know, are close together locations. BMS is trying to avoid this idea that you're making a unique selection of peaks or comparison that is going to show this is a product that's unique to monohydrate. They have suggested that their peaks get a pretty large range, and that relative peak intensity is irrelevant. And they're saying, you know, by the way, give us more variation based on specified measurement errors and the like.

So, you know, the more different sources of variation they try to put into what Figure 1 could look like -- and then that, of course, begs the question of when you're doing the comparison to Figure 1 do you compare to the top part of the pattern? Do you compare to the bottom part of the pattern? You know, what if a person of ordinary skill in the art sees a peak that matches one, but not the other? Do you say it is the same? Do you say it is different? These are all things that really are fundamentally left unresolved by the claim language itself.

So, that's why, you know, in the end the "substantially

similar" phrase, you know, it really does come down to what we believe is a very subjective judgment, even on the part of the person of ordinary skill in the art because there's no guarantee that people are going to consider the same measurement errors or the same visual differences to essentially be describing the same crystal form.

So, if we go then to Claim 3, here, again, I think that this point really starts to come to the fold because now they're only focusing on selecting from the group consisting of 18.0 plus or minus .2, 18.4, 19.2, 19.6 with a plus or minus .2 variations, et cetera. All of those red lines that we drew in on Slide Numbers 7, 9, 10, 11, all of those correspond to one or more of those particular peaks that are identified in Figure 1. So when you have, you know, four, five, or six peaks from the monohydrate and the butanol solvate being -- you know, these overlapping ranges, then really how good are these peaks? And then that kind of begs the question of, well, what is it then, what function are these peak descriptions really supposed to serve in the context of the claims?

And if we can jump to Slide Number 20...

You know, counsel said, Well, we're still going to have to prove that this substance is a monohydrate that's further characterized by various peaks. Well, their expert Dr. Atwood admitted that if you have a genuine crystalline monohydrate

sample you're going to have all eight peaks. So then that leads us to say, Well, then what's the rationale then for saying we're only going to say you have to have four or more? If you genuinely do have a monohydrate crystal, inherently that crystal form should have all of those peaks, and they should have clearly discernable intensities in the X-ray diffraction pattern.

THE COURT: Just -- if you would put on your tutor hat for a second -- and I'm sure your adversary will correct you if you're wrong -- if you go back, please, to Figure 1 --

MS. MAZZOCHI: Yes.

THE COURT: -- which does show an X-ray printout. I'm just going to call it an X-ray printout, okay?

MS. MAZZOCHI: Sure.

THE COURT: I'm just trying to capture for the record the interrelationship between this Markush group that we see, for example, in Claim 3 and the actual X-ray printout, only because it's not intuitive to me where something like 18.0 plus or minus is found on an X-ray printout.

MS. MAZZOCHI: Sure. Okay.

THE COURT: And, also, while you're at it, if you would show me the magic eight peaks that you can at least see in Figure 1 that the patent sets forth as an example of its crystal.

MS. MAZZOCHI: Yes. And, actually, Your Honor, what

might be easier for me because then I can do some of the comparisons with regard to the eight peaks, if we can jump to Slide Number 11 and blow this pattern up. We can start with Figure 1.

THE COURT: And this shouldn't take long, but just we'll capture this for the record.

MS. MAZZOCHI: Sure. Okay. Let's start here, for example. This is -- on the x-axis it is the Number 18. And one of the peaks that appears in -- that's listed in Claim 3 is 18.0 plus or minus .2. Well, if we look here at 18, we can see -- because it is one of the tallest peaks in the pattern, if not the tallest -- we see at the very top of the peak this is a clear signal. You know, it is not something that's -- sometimes in these polymorph crystal form cases you have debates over whether something is really a peak in the X-ray pattern, it is rising above noise -- background noise. There's no question of this being the tallest peak in the pattern. It is a real peak. It is a real response. And it is exactly where it is supposed to be at 18.0 in this particular X-ray diffraction pattern.

So, then if we start moving over on the scale -- if you go down from this very tall peak, you'll see there's a second peak, and this is one that's -- this is the peak that's at 18.4. So, it is a shorter peak. It is only going maybe a fourth or maybe a third of the way up the peak to its

immediate left, but it is still -- it is clearly not noise. It is something that's discernable above the background.

THE COURT: And that's at location 18.4.

MS. MAZZOCHI: Right. Unfortunately, Figure 1 it only has the vertical lines on the x-axis going in increments of 2, so it is harder to figure out. Yeah, in theory, if you blew it up you could measure out tick marks exactly and try to get a little bit more precision.

THE COURT: I get the idea. So, 18.4 would be, basically, almost halfway between 18 and 19.

MS. MAZZOCHI: Exactly.

THE COURT: Okay. Fine.

MS. MAZZOCHI: So then if you look here where we've got our first vertical red line in Slide Number 11, this is the peak that the -- that Claim 3 would assign for the monohydrate as 19.2.

So, you know, if you look at the x-axis it is appearing roughly halfway between 18 and 20, again, because Figure 1 is printed rather small in the patent. If you blew it up, again, and you started drawing it out, you should be able to see here, again, a very clear peak that's not noise at 19.2.

Then the next red line over would be -- because it is appearing now roughly between, you know, 19 and 20, this is the one -- the peak that's at 19.6.

THE COURT: Okay. I get the idea.

MS. MAZZOCHI: Right.

THE COURT: So, these numbers, 18, 19, et cetera, refer to the horizontal measurement --

MS. MAZZOCHI: Exactly.

THE COURT: -- in that Figure.

MS. MAZZOCHI: Yes. The horizontal measurement in the pattern -- and that's typically referred to in degrees 2 theta. So, the number 2 and then the circle with the line through it.

THE COURT: Just a second. Yes, that's what I don't understand. The 2 theta is what?

MS. MAZZOCHI: The 2 theta -- on the x-axis, the 2 theta, what that's ultimately corresponding to is it is telling you when you ran the X-ray diffraction test -- and, again, this all kind of gets back to Bragg's Law and how you measure the angle of the scattered X-rays -- but, essentially, it is an angular measurement.

THE COURT: Angular measurement. The 2 theta is an angular measurement.

MS. MAZZOCHI: Well --

THE COURT: It is part of an angular measurement.

MS. MAZZOCHI: Let's call it a consequence of measuring the sample at various angles.

THE COURT: Okay. Go ahead. But not much more information.

MS. MAZZOCHI: Sure. So, anyway, so looking here then in the Figure 1 of the '725 Patent that we have on our Slide Number 11, then, again, as we start going through some of the peak 2 theta values that appear in Claim 3, we have 21.2. There's another -- so, which we didn't do the red line. And we have got 24.5. So that's where this one, two, three -- the fourth red line over from the left appears. Then they list in claim 325.9. So, that's this peak that appears here where we've got a red line. That's second from the right-hand side. And then Claim 3 also refers to 28.0 plus or minus .2. Here, again, we see a noticeable peak, and that's why we drew the red line there.

THE COURT: And this plus or minus .2 would refer to the location of the peak on that horizontal axis.

MS. MAZZOCHI: Exactly. So, what they're basically trying to do, instead of saying, Here's our thin red line, let's make it a thick red line, and anything within the range plus or minus .2 of the thin red line, they're saying that's what we get to cover. Any peak that shows up within that range we're going to say that's one of the peaks of Claim 3.

THE COURT: Now here's a simple question, I hope: When I read this language in Claim 3 "comprising four or more 20 theta values selected from the group."

MS. MAZZOCHI: Right.

THE COURT: Does 20 theta values refer to the fact

you're going to see a peak there?

MS. MAZZOCHI: Well, that's one of the issues we have with the plaintiffs.

THE COURT: Well, but, I mean, something has to tell us that you're looking for a peak at 18.0 plus or minus .2.

MS. MAZZOCHI: See, that's one of the things that's unclear about Claim 3 is it says, "crystal monohydrate of the compound of formula (IV)," fine, "which is characterized by an X-ray powder diffraction pattern comprising four or more 2 theta values." You would think that might be requiring a peak, but they don't say "peak." They just say "2 theta values." So, does that mean that if you just have an X-ray powder diffraction pattern that's got, you know, "18.0" written on it that you've now complied with Claim 3?

So, no, that's why we said in our brief we thought that 2 theta values, what the heck does that mean? It is really an indefinite term. When people are usually talking about what you see in an X-ray diffraction pattern you're talking about seeing a peak, and a peak is usually something -- you say it is a meaningful response that rises more than two -- you know, two times the noise and all that kind of stuff. And there's actually case law where -- it is the Abbott v. Lupin case that was in the Eastern District of Virginia before Judge Payne where he actually construed the term "peak" in the context of an X-ray diffraction pattern as something that rises up and

goes back down and is not part of the noise. That was the cefdinir litigation that I was involved in for Lupin.

So, for example, if you were to look at this -- this Figure 1 of the '725 Patent, if you look here at the number 6 2 theta, for example, you know, yeah, the value of 6 is certainly set forth here in the patent, but you don't see a peak there. You don't see any intensity there.

THE COURT: There's nothing there. It is flat.

MS. MAZZOCHI: There's nothing there. It is flat.

So, when the plaintiffs turn around and then say, Oh, intensity shouldn't matter when you're talking about, you know, these values that they put in Figure 3 it is like, well, they have to matter. You have to be talking about some type of peak or intensity.

THE COURT: I don't think they say intensity doesn't matter. I think they say you're going to see differences in degree of intensity.

MS. MAZZOCHI: Well, but let's actually jump --

THE COURT: I think that's what they're saying.

All right. I'm done with my question.

MS. MAZZOCHI: Sure. Well, if I may, let me jump to one of the statements by their -- by Dr. Atwood. This is at our Slide Number 21. I asked him, It is your opinion that you need to look at these peak numbers in Claim 3 without regard to their intensity, right, or their relative intensities? He

said, In Claim 3, yes. Claim 3 is totally silent about relative intensity.

So, you know -- so, when we have their expert saying Claim 3 is totally silent about relative intensity and they want to say, you know, Oh, we don't need -- these peaks don't necessarily need to uniquely identify the monohydrate. Well, then what is it then that these -- that's why I get back to the same question -- what is it then these peaks are there to do? If they're there to characterize the monohydrate, then they have to be, you know, what are really some of the biggest peaks in the X-ray diffraction pattern, and they are supposed to be showing up in reliable, reproducible locations. Dr. Atwood says if you've got a true sample of the crystal monohydrate, all eight peaks should be there. Well, if all eight peaks should be there then why are you saying we only need to select four of them? And, you know, that's why we get concerned that what they're really trying to do -- if we can jump back to that Slide Number 11 -- is what they're really trying to do through the back door is they're trying to get at -- include Figure 6, as well -- what they're trying to get at is they're trying to get through the back door other polymorphic forms that are totally different polymorphic forms, but they may still have multiple peaks in locations. You know, are they going to say those are substantially similar locations? Are they going to be within plus or minus

.2? Are they going to be within the range of measurement error?

You know, what Claim 3 is really doing is -- to me, it is either one of two things. Either these new descriptive items that they have added on to Claim 3 don't do anything because a true crystal monohydrate sample is going to cover it, or are they really trying to say, We get to cover monohydrate for any -- or we're going to get to cover, basically, any product that we can say has Dasatinib in it where you see four or more of these peaks, because if that's what they're going to say that's how we discharge our burden of proof on Claim 3.

You know, here's a sample, and, you know, whether it is an Apotex sample or some other generic sample, whether it is, you know, tablet, raw material, whatever. Are they going to turn around and say, Well, we took an X-ray powder diffraction pattern of this tablet -- for example -- we think we see four peaks that are on our list in Claim 3. That's it. You know, you say you've got Dasatinib in it, that's it; therefore, we think you infringe. Well, no, that's really --

THE COURT: Your burden of proof on what, as a defendant?

MS. MAZZOCHI: No, their burden --

THE COURT: Oh.

MS. MAZZOCHI: -- as a plaintiff.

THE COURT: You're speaking for them.

MS. MAZZOCHI: Right, yeah. You know, I mean -- and that's one of our major concerns is that, you know, because they keep on trying to push for these broad numbers and these broad ranges that overlap with other polymorphs they don't want to say that these -- these peaks are going to be -- so, for example, if they said these peaks that we see in these positions they have to be real peaks, and we're going to come forward, and we're going to prove that whatever that signal intensity, or value, or however they want to call it, that it is there only because of monohydrate, that's one thing. But they're not trying to go in that direction. They're trying to read this very expansively. So, our concern is that what they're really trying to do is cover compositions that actually do have these other polymorphic forms in them and actually --

THE COURT: But if they are that favors you, I suppose, when you say it cannot be. But today we're on construction.

MS. MAZZOCHI: Right. And one other point I did want to make. One of the peaks that's at 18 -- it is somewhere in our slides -- Dr. Atwood admitted that you're going to get a tall peak in the PXRD pattern if you're just using one of the very common pharmaceutical excipients known as lactose.

So, again, you know, they're trying to say that Claim 3

it is, you know, not limited to a raw material. It is not something necessarily made by the process conditions set forth in their patent. They're trying to say, you know, it doesn't have to have all eight. Maybe it has all four. There's no restrictions on intensity. Well, you know, as you start to do that, that is precisely what renders the claims that much less definite because now they can cover other polymorphs. They can include pharmaceutical excipients.

THE COURT: I got that point.

MS. MAZZOCHI: Yeah. So, then -- and one point I did want to make, they talked about the relative -- I'm sorry, the preferred orientation issue.

Let's just jump to Slide Number 23.

The mometasone case that they cited before Judge Sheridan that was a case that I tried. Gosh, it was earlier this year.

THE COURT: What case?

MS. MAZZOCHI: It is Schering Corporation versus Apotex, 2012 Westlaw.

THE COURT: That's fine. It is cited on your Slide 23.

MS. MAZZOCHI: Yes. What our expert -- that was Dr. Cobcroft (ph) -- was saying in that case is that the brand pharmaceutical company, Apotex, was making a non-infringing drug product, non-infringing polymorph. Schering was coming

forward, and they were trying to say they thought they saw some trace quantities of infringing polymorph, which was a monohydrate, in our non-infringing polymorph.

The problem is that the occasional peaks that they were finding in the X-ray powder diffraction pattern, to the extent they overlapped with monohydrate, many of the other peaks that were also characteristic for monohydrate that were much bigger than those peaks were missing from the X-ray diffraction pattern. So, our experts looked at Schering's work and said, No, you haven't proved that there's any monohydrate in there because if you're seeing something that in a normal pattern is a really, really little peak, and there should be a really, really big peak and that's missing, then whatever that little tiny peak is it is not monohydrate.

Schering's expert came back and tried to rebut that position by saying, Well, I think it is still a monohydrate crystal, but it's got such extreme preferred orientation that those peaks have gone missing. All our expert was doing in the quotation that the plaintiffs cited here is he said, No, no, no, you're never going to have the situation where these crystals are going to -- in a real world sample are going to lead to peaks that completely disappear. You're always going to have some signal intensity. So, he is not suggesting here that, you know, you should expect to have really, really low intensity in any of these peaks; all he was saying, basically,

is the theory that Schering's expert was trying to put out there as to why those peaks were missing was, basically, absurd. It is not going to work. It would be the equivalent of saying, I'm going to throw a hundred pennies up in the air, and they're all going to land perfectly on their edges on their sides, and that's what's going to cause the peaks to disappear. So, completely different scenario from the intensity concerns that we had here.

THE COURT: I'm not sure what you're getting at, but I'll take it.

MS. MAZZOCHI: That's fine.

THE COURT: You're saying you've got to have more than just four peaks to make this compound monohydrate show up on an X-ray printout.

MS. MAZZOCHI: Yeah. It is not only that --

THE COURT: Is that what you're saying?

MS. MAZZOCHI: Their expert said if you really do have monohydrate you're not only going to have four, you're going to have all eight.

THE COURT: That's right.

MS. MAZZOCHI: Right. So if you know you're going to have all eight, if you have truly got a monohydrate crystal -- and what they're really trying to cover is a monohydrate crystal -- then why are they trying to cut it back to four?

THE COURT: Don't know.

MS. MAZZOCHI: Right. And, you know, so -- and that's why from our perspective if they're trying to say that some of the peaks are allowed to go missing then you don't have a monohydrate sample anymore or you certainly can't prove you have got a monohydrate sampling anymore.

THE COURT: If I sat the two of you across from each other at a table, the two sides, and said just show me the eight basic peaks in Figure 1, could you do that?

MS. MAZZOCHI: Well, yeah, we could certainly -- it depends on which peaks you want to focus on, but if you wanted to say, Show me the eight most intense peaks --

THE COURT: Yes.

MS. MAZZOCHI: -- you could just take a ruler and just actually move it down and say, All right, there. You know, we have one, two, three, four. Shift it down a little bit more. Five, six, seven, eight. Not necessarily going to be these same eight is the most intense peaks because, you know, that's the other thing. With regard to these particular peaks they have listed in Claim 3, you know, they do have -- you know, you can go through that same exercise with the ruler for the butanol solvate, and you might find some of the peaks on this Claim 3 list in the butanol solvate, which is clearly not the monohydrate. You could go through the same exercise and find some of the peaks in the list in Claim 3 in an anhydrate sample, which is not a monohydrate. And the ethanol

solvate, which is not a monohydrate.

So, you know, maybe the better question is to ask them why they need to have only four and why they're not going to try to come forward and try to prove all the eight.

THE COURT: Okay. So, that's Slide 24, as well.

MS. MAZZOCHI: Yes.

THE COURT: And 25.

MS. MAZZOCHI: Right. And, actually, we can just go ahead and at this stage jump to --

THE COURT: We do ask that any discussion behind has to be below the audible level.

MS. BEN-AMI: I'm sorry, Your Honor. I apologize.

MS. MAZZOCHI: So, why don't we jump to Claim 5 of the '725 Patent, which starts at our Slide Number 28. We have got the language.

Now, Claim 5 is different because this testing that it is describing here where it has -- what it calls "cell dimensions," that's signaling that it is the result of a single crystal X-ray diffraction test. A single crystal X-ray diffraction test it is sometimes abbreviated as SCXRD in distinction to powder X-ray diffraction testing, which is abbreviated PXRD.

In single crystal analysis what you actually have is you have one tiny little -- you know, think of it as the grain of sand. You mount it into the sample holder. And then

you -- you do subject it to X-rays, but it is a totally different type of X-ray test. And what you actually wind up doing is you look at -- probably the best way to describe it is almost a full 360-degree analysis throughout the entire sphere around the crystal, almost as if --

THE COURT: Looking at it from every angle.

MS. MAZZOCHI: Every angle. And, in fact, we have got a picture of what that apparatus looks like on Slide Number 32.

So, you know, this one -- so, you've got it mounted in the sample holder. You rotate it to get, you know, one direction. You've got the base rotating. You have got the X-ray turning around. So, you've got the detectors that are also rotating. So, you really are trying to look at it globally for lack of a better phrase.

Now, because you do that it allows you to get -- if you've got a properly grown and properly selected single crystal that doesn't have what are referred to as crystal defects, it is of a sufficient size, et cetera. That's what allows you to collect some of the data that's referred to in Claim 5.

THE COURT: Hang on. Where is your sample in the schematic on Slide 32?

MS. MAZZOCHI: Right here (indicating). That little blue cylinder in the middle.

THE COURT: So, it is in there.

MS. MAZZOCHI: Yes.

THE COURT: Okay. Fine.

MS. MAZZOCHI: So, basically, the grain of sand gets fixed inside, you know, the holder, and it gets spun around. Everything gets spun around to try to look at it from every single conceivable direction.

So, then when you do that -- and, again, if you've got a good crystal there are many instances where you can select a crystal, put it in there, it is just not good enough or high quality enough or uniform enough where you can actually get a good read off the crystal.

So, if we jump back to the Claim 5 language, what they, basically, said here is we've done this single -- this, you know, special single crystal analysis, and from this we've determined that the unit cell has certain dimensions, a, b, and c. So, think of that as equivalent to length, width, height. We can make that assumption because it is described as space group Pbca. In single crystal X-ray land that's defining a certain type of geometry for the unit cell, which is kind of like -- basically, think of it like a rectangular box.

So, this is, basically, telling you, you know, one box has a length that's the 13.8632(7). Then, you know, different dimension for b and different dimension for c. Then you

basically multiply these up, and that's how you get the volume that's within the unit cell. And then this is also telling you that within your unit cell you're actually going to have --

THE COURT: Is the "a" what you're solving for?

MS. MAZZOCHI: No. This "a" -- the reason why in single crystal X-ray analysis they use a, b, c, and then you can also have a box -- if you were to think of a shoe box and maybe started to squish it so that two of the sides are angled, they also have what are referred to as alpha, beta, gamma measurements, which measure the angles that you have squished the thing over.

Here for this particular space group we don't need that because what -- that's what -- what they're, basically, telling you is that the shape of the unit cell is like a shoe box.

THE COURT: Okay. That A has a little circle attached to the top of it.

MS. MAZZOCHI: What that is -- oh, yes, I'm sorry.

THE COURT: The capital A that's inside the parentheses in each of subsets of a, b, and c.

MS. MAZZOCHI: What that is is that is angstroms, A-N-G-S-T-R-O-M-S. Because you're looking at molecules and they are so small sizewise it would be impractical to use things like meters, or inches, millimeters. So angstroms --

THE COURT: Is a unit of measurement.

MS. MAZZOCHI: -- is a unit of measure. Basically, very, very small.

THE COURT: Tiny measure.

MS. MAZZOCHI: Exactly.

THE COURT: Okay.

MS. MAZZOCHI: To give an example, a typical bond length between atoms is on the order of maybe one to two angstroms, depending on the type of bond.

THE COURT: All right.

MS. MAZZOCHI: So here, you know, they, basically, have said that this is the -- so this is the size of our unit cell box. They have told you because it is a space group Pbca that it essentially is that kind of box. Then when they say molecules per unit cell, because this is a monohydrate, so you've got one molecule of water for every molecule of Dasatinib, that means you've got four molecules of water, four molecules of Dasatinib. If this is genuinely a monohydrate crystal. And then --

THE COURT: So, molecules per unit cell, eight.

MS. MAZZOCHI: Right.

THE COURT: Says four Dasatinib and four water.

MS. MAZZOCHI: Yes. If we, basically, assume that the Dasatinib, you know, hasn't itself bonded to the water then you would have -- for a monohydrate if you say you've got

Dasatinib monohydrate there's eight molecules in a unit cell, then you, basically, split them. So you would say four molecules, four Dasatinibs. And then based on the amount -- the weight amount of those molecules in the unit cell that's how they -- then they get the density measurement, as well.

It used to be, say, back in the 1950's and 60's doing a single crystal cell -- a single crystal test, like that could be your thesis. Or you could spend years trying to figure it out. Today the technology has gotten much more advanced and computerized, so now sometimes if you've got a really good crystal you can solve an equation in a matter of days or weeks.

But ultimately, you know -- so what we know from this then is that these types of measurements show that whatever the sample was it was a single crystal. And one of the concerns that we have then with this is that, you know, first it says, "the compound of Claim 3." All right. Now, if the compound of Claim 3 is just that part (indicating) --

MS. BEN-AMI: We argued that already.

THE COURT: You're not making a record when you go point at something.

MS. MAZZOCHI: I'm just saying if it is just that compound --

MS. BEN-AMI: Your Honor, can I object at this point? We argued this point at the last Markman session.

MS. MAZZOCHI: I'm not going to revisit that. I'm just showing why in the context of Claim 5 we have a problem.

THE COURT: Okay. It is okay just to refresh our collective recollection about something and then pick up from there.

MS. BEN-AMI: Thank you, Your Honor.

MS. MAZZOCHI: Sure. So, under --

THE COURT: When you went to the board you were just simply referring to the chemical diagram of Claim 1.

MS. MAZZOCHI: Right. The one that's denoted with the parentheses Roman numeral IV. And it also appears in Claim 3 that compound of formula (IV).

So, if you just take Claim 5 then at face value where it says, "the compound of Claim 3 characterized by these unit cell parameters," here where you see molecules per unit cell eight, now, that could be signaling that you've got eight Dasatinib molecules packed into the shoe box. So, the construction of the compound of Claim 3 is also going to influence what does it mean to have molecules per unit cell.

THE COURT: Molecules of what?

MS. MAZZOCHI: Exactly. So, if compound of Claim 3 is equated to -- you know, and then, well, I guess, actually under plaintiffs' construction if you equate compound of Claim 3 to crystalline monohydrate then they might be implying that you've packed eight monohydrate molecules into the unit cell.

You know, I don't think that would necessarily be right, but scientifically speaking in terms of what you get off a single crystal test -- but, you know, that being said...

THE COURT: Is that on a slide here somewhere?

MS. MAZZOCHI: In terms of the molecules per unit cell? Well, actually, Your Honor, let's see. I might be able to illustrate this if we took --

THE COURT: Slide 34?

MS. MAZZOCHI: And, actually, I'm glad you jumped right to that. Yes. Dr. Atwood, he actually said that the unit cell parameter information -- if you were, basically, to hand Dr. Atwood those unit cell things in Claim 5 and just ignore the compound of Claim 3 and say, Here are these parameters; can you tell me if this a monohydrate or an anhydrate? He said, No, you can't tell.

THE COURT: Okay.

MS. MAZZOCHI: So, yes. So what they, basically, told you in Claim 5 is they've said here is the density of the shoe box, here is the size of the shoe box, we're telling you you've got a shoe box, but they don't give you the details necessarily of exactly how things are truly arranged within the shoe box and going forward.

So, you know, so then, again, when it comes to Claim 5 because it is dependent on Claim 3, so if Claim 3 is calling for a crystalline monohydrate, but if Claim 5 can be construed

to the point where it would permit just an anhydrate crystal to be in the shoe box, then you have an improper dependency problem because a dependent claim can't be broader than the underlying claim that it depends from. That's Pfizer v. Ranbaxy.

THE COURT: Well, we know that. But when they say, "the compound of Claim 3" when they start out Claim 5 that is a hint that it is dependent -- and refers at least to the same compound.

MS. MAZZOCHI: Right. So to the same compound, but it didn't say the crystalline monohydrate of Claim 3, et cetera.

Similarly, to the extent Claim 5 is referring to a single crystal test result, you know, because it is, for lack of a better phrase, the grain of sand that you have plucked off the beach, Claim 3 when it is talking about a powder X-ray diffraction test that's, basically, you know, we're bombarding the beach with the X-rays.

So, you've got a powder sample versus a single crystal sample. When you do single crystal analysis, you know, you have to be very careful that if you -- even if you start with a powder sample and you try to just pluck a crystal out of it is it necessarily representative of all the other crystals that are in there? So if you pick out a really big crystal -- well, if a lot of the other crystals are really small and

powdery is that big crystal really representative of the powder and vice versa?

So, you know, because they're talking about these two different types of tests -- you know, when it comes to the type of sample that's being analyzed they're really kind of mixing apples and oranges in the sense that, you know, yes, both tests involve X-rays, but the powder diffraction test you're dealing with a bulk sample; single crystal test, that's the special sample. You know, many times they're actually uniquely grown for that experiment. So it really doesn't make sense to try to say, We're going to characterize our bulk pharmaceutical product by looking at a single crystal X-ray analysis.

That's why, you know, Claim 5, given its dependent status on Claim 3, the way it is written, the information that it does and doesn't provide, again, that's why we have some concerns with whether it is -- you know, what is it defining, and is what it is defining really going beyond Claim 3, such that it would create a separate invalidity problem.

And, again, just saying, Well, look at the ordinary meaning of Claim 5, that doesn't really address the concerns. But, again, you know, I don't think that that issue necessarily needs to get raised today in part of claim construction, but, you know, we did want to raise these issues so that, you know, there was no argument later that we had

waived them.

And I think then -- one thing I did want to note. If we can just jump to --

THE COURT: If you don't mind just at this point I will hear a response on all of this material, but we are going to take our recess before the response, so that it won't be pushed.

MS. BEN-AMI: Thank you, Your Honor.

MS. MAZZOCHI: One other item, if we can jump to our Slide Number 35 when it comes to this question of what does it mean to be approximately equal? One thing I did want to note is that I asked Dr. Atwood, their expert, how big of a standard deviation do you need before you're going to call, you know, variations to these unit cell parameters and angstroms a different crystal structure? He proposed a hundredth of an angstrom. I haven't seen any literature citation that they relied on if that's, you know, going to be their theory as to what constitutes approximately equal. But I do want to note that if we jump to Slide Number 36 there is a published paper purportedly trying to describe a Dasatinib hydrate -- and including a monohydrate -- where if you look at the published values of the dimensions of the shoe box, if you will, they actually do vary by more than a hundredth of an angstrom that Dr. Atwood said would constitute approximately equal.

So, if Dr. Atwood's standard is to be applied, there could very well be multiple monohydrate crystals. And, again, then coming around full circle when we start talking about what does it mean then to uniquely identify the '725 Patent monohydrate crystal, you know, the types of wide measurement errors that the plaintiffs, for example, in Claim 3 want to give themselves, once again, may not be capable of uniquely characterizing the actual '725 Patent monohydrate crystals.

So, I think that is the X-ray presentation.

THE COURT: Thank you. We'll just take 10 minutes.

(Break taken from 11:18 to 11:32 a.m.)

THE COURT: Thank you. What is next?

MS. BEN-AMI: Your Honor, I think you said I could respond to the comments made by counsel.

And, so, I will try to do this as quickly as I can. But counsel ended her presentation by saying she was voicing her concerns about the patent. And I have some concerns. My concern is about the presentation we just heard. There was a lot of scientific discussion there that is not evidence. It is argument. And it is about issues that are for another day.

This is a claim construction hearing. And today what we're supposed to be doing is discussing what the claims mean in light of the law. And Your Honor knows the law. First you're supposed to consider the ordinary meaning. You're supposed to consider the specification. There are rules of

claim construction, and you're supposed to use those rules to construe the claim. And, frankly, Your Honor, in the entire presentation I didn't hear those rules being applied or considered. I heard a lot about, well, maybe this and maybe that, and maybe the other thing, but I didn't hear a lot about true claim construction.

THE COURT: I had no trouble sorting out that.

MS. BEN-AMI: So I would like to get back to claim construction, okay?

THE COURT: The science was just for me to understand, you know, what does "theta" mean and where are these peaks at and that kind of thing.

MS. BEN-AMI: That was part of it, but part of it was when it says you're going to look at a peak from a butanol sample and say it is a monohydrate, no, that's not how it works. And we don't need to do that today because today we're doing claim construction.

And, so, you know, but when I was listening to counsel I was left with the impression that counsel was saying that if you follow the claim construction and you use this testing -- and, remember, the claim says plus or minus .2, that, you know, that's a bizarre thing, it would be worthless, it is not what someone skilled in the art would do. But I would ask Your Honor to look at our Slide 120. Can I have that, please?

And I do this because I'm not here to testify. But I

want to give Your Honor some comfort that when you do hear the testimony from the sworn experts it may not match everything you've heard today. And their expert confirmed that a plus or minus .2 would be a standard deviation. It is used by several people. Yes, it is used. And, in fact, he has a patent where he uses the same plus or minus .2. And where it says using -- "characterizing something using at least three of the following reflexes." So the structure of the -- his claim says, "use at least three," just like we said "four or more plus or minus .2," just like our claim says, "plus or minus .2." This is the way this field works.

And all the argument about, well, you know, this is a parade of horribles. It is just not going to be consistent with the actual evidence that you hear in the future. And I just show you this so you have some comfort that these claims are not something wildly abnormal.

THE COURT: Even if they were, it wouldn't change my claim construction if it pertains to issues of invalidity, for example.

MS. BEN-AMI: Thank you, Your Honor.

THE COURT: I'm here to try to understand enough to be able to do a decent claim construction.

MS. BEN-AMI: Right. But here the claims say what they say, and that's why we say to a certain extent there is a plain meaning. If the claim says plus or minus .2, it is plus

or minus .2.

But counsel also said she couldn't understand a lot of the words in the claims because of her reading. Well, is the 2 theta value meant to be a peak or is it -- when it is a flat line? So I ask Your Honor -- I don't know if you have the '425 Patent still?

THE COURT: Yes, I do.

MS. BEN-AMI: If you look at Column 44.

THE COURT: Just a minute. The '425?

MS. BEN-AMI: The '725 Patent.

THE COURT: I have them all here. What column?

MS. BEN-AMI: 44.

THE COURT: One moment.

MS. BEN-AMI: If you look on Line 23 it starts, "One of ordinary skill in the art will appreciate that the monohydrate of the compound of formula (IV) may be represented by the XRPD as shown in Figure 1 or by a representative sampling of peaks as shown in Table 1. Representative peaks taken from the XRPD of the monohydrate of the compound of formula (IV) are shown in Table 1" and then there's a table. And then it goes on and really states pretty much what's in one of the claims, I think Claim 3.

So, we don't need to guess about 2 theta values and what they mean, that it is the flat line. The specification tells us what we're talking about. This is the primary --

THE COURT: Okay. Just since we're on Table 1 --

MS. BEN-AMI: Yes, ma'am.

THE COURT: -- the middle column is headed up lower case "d," paren, "(Å)," which is the symbol capital A with a little circle on top, closed paren. And the third column is entitled "Height." And the first column is called "2 theta."

MS. BEN-AMI: Right.

THE COURT: Can you just tell me from the evidence, as you understand it, height is height of a peak --

MS. BEN-AMI: Right.

THE COURT: -- in some kind of unit of measurement.

MS. BEN-AMI: Yes.

THE COURT: 915, et cetera. So they can measure the height of the peak.

MS. BEN-AMI: Uh-huh.

THE COURT: But what are these other two columns, the "d(Å)" and the "2 theta"?

MS. BEN-AMI: Well, the 2 theta we talked about already, right? And we remember when we looked at that picture it was the horizontal line on the figure, right? We looked at this, the horizontal axis called the x-axis.

THE COURT: Right.

MS. BEN-AMI: And those are based on the angles of the diffraction, right. And counsel went through the Bragg's equation and all that, but we don't need to really get into

that kind of detail. What this is saying is you -- you cannot do this. All right. There we go. You are -- it is telling you here are your 2 theta values. Right?

THE COURT: If you say so. Referring to the scale numbered one through --

MS. BEN-AMI: 32.

THE COURT: -- 32 on the horizontal or x-axis, right?

MS. BEN-AMI: Right. So you'll see the 2 theta value in Table 1 is 17.994.

THE COURT: That's the location on the line.

MS. BEN-AMI: Right.

THE COURT: It is that simple.

MS. BEN-AMI: Yes.

THE COURT: Thank you.

MS. BEN-AMI: That's it. That's all you need to know.

THE COURT: That's all I want to know. Okay. Horizontal location on the line.

MS. BEN-AMI: Right. And then when you look below it says, "selected from here 17.9 plus or minus .2." All right? And then it says, "it can also be selected" --

THE COURT: But that's not my question.

MS. BEN-AMI: Okay.

THE COURT: So, the middle column, the "d(Å)," I don't need to know what that's telling me.

MS. BEN-AMI: I can't -- all I know from counsel my co-counsel is that can be converted into the 2 theta, but it is not in any of the claims.

THE COURT: Okay. Fine. Fine.

MS. BEN-AMI: So I think that we're safe. But my point here is it is not -- when they talk about 2 theta values they're clearly talking about peaks because that's what the specification tells you. All right?

THE COURT: So, there's going to be a peak at that horizontal location.

MS. BEN-AMI: It is not going to be flat. It is going to be a bump, a peak, however you want to characterize it.

THE COURT: And if you want to know about a peak you might want to ask its height, which we have a column of measured heights on Table 1.

MS. BEN-AMI: That is right. There are measured heights in Table 1, but we remember from the specification that those are not absolutes.

THE COURT: Right. And that's called "intensity of the peak," right?

MS. BEN-AMI: Right. That's right.

THE COURT: It means height.

MS. BEN-AMI: That's it.

THE COURT: Thank you. Go on.

MS. BEN-AMI: That's why these claims are really they're not -- there's not that much construction needed at the end of the day.

And then if you look going forward like at Line 49 in that same column, counsel was saying, Well, we don't know if the single crystal X-ray data is of a monohydrate. Remember she was talking about I think it was Claim 5?

THE COURT: Either 3 or 5.

MS. BEN-AMI: It is not on here. It is not on this picture. But, you know, well, is Claim 5 really about the monohydrate or is it not the monohydrate? Well, we can look in the specification again, right there (indicating). And it tells you. "Single crystal X-ray data was obtained at room temperature (plus 25° C). The molecular structure was confirmed as the monohydrate form of the compound of formula (IV)." And then it goes forward and has those kind of numbers that we saw before.

So, when we apply the rules of claim construction we take the ordinary meaning of the terms. We say is there something that needs to be construed? So if we look at Claim 1, we haven't had much of an issue about crystalline monohydrate. We talked about those issues before. We have the formula, which is characterized. We know what Figure 1 is. The Court -- so in terms of claim construction the only question is really should be substantially in accordance, and

we have shown what you the specification said. And we have shown you that the Courts have allowed "substantially in accordance" as a term routinely.

So, I think fundamentally when I listened to the argument that was made there was -- it was confusing to me because it seemed scientifically confusing to go ahead and look at two -- you remember counsel had two charts. One was a monohydrate chart, and one was, I think, a butanol solvate chart and said, Look, they have one peak, they share a peak. Well, that's fine. Maybe they share a peak. But that doesn't mean they have the same pattern. Just because they have one shared peak or two shared peaks. And the important thing here of this claim is -- and I keep saying it, this is not a claim to an unknown.

THE COURT: Please. I have got that part.

MS. BEN-AMI: So all we need to do here is say is it a crystalline monohydrate? We have to prove that later on some day in the future, right? We have to prove these parts. But for claim construction I don't think any of that is really relevant because the claim construction is clear. I took a lot of notes about what I was hearing, but I'm trying to not go over a great deal of information that I don't think really goes to claim construction.

THE COURT: Fine. Another simple question.

MS. BEN-AMI: Sure.

THE COURT: If I had a pile of stuff, and I wanted to make -- and I wanted to make sure it was crystalline monohydrate of this compound, could I find that out without using X-ray powder diffraction and unit cell single cell X-ray diffraction methods? I mean, is there --

MS. BEN-AMI: There are other tests that one can use in conjunction, and I think you -- I mean, the first thing, I am not a scientist, but I'll tell you my understanding. If I turn out to be wrong in the future, I apologize, because --

THE COURT: Well, you start out with a beaker of a compound. You know it is your compound, right?

MS. BEN-AMI: Yes, we know it is the compound.

THE COURT: Then you get it out of amorphous into some crystalline form?

MS. BEN-AMI: It is crystallized, yes.

THE COURT: And then you have to make sure it is a monohydrate crystal.

MS. BEN-AMI: That's correct, also. So, I mean, there's no argument here really with -- I don't want to go into the confidential information, but as Your Honor knows, we have a label to the monohydrate of Dasatinib, and they are trying to sell under that label. So, when we get to the evidence you'll see the evidence on that, but, you know, you can take a molecule apart and see how many carbons it has and see how many nitrogens. That's one thing you do. You look at

the melting temperature. You look at various other tests. There are a whole bunch of other tests one can do. And, so, here we're saying it is the crystalline monohydrate, and that's step one because that's Claim Element 1, right, and it is going to be characterized by this specific test in this specific way.

THE COURT: Thank you.

MS. BEN-AMI: And we're going to see later on while we can look at Slide 12, right, there's a different method that's going to be addressed. So, I mean that's the way it works. But it will always be our burden of proof to prove that they had the crystalline monohydrate.

Counsel argued about improper dependency and whatnot. I think, again, if you read the specification, as I just showed you, it is clear it is the monohydrate. There's no improper dependency.

Honestly, Your Honor, having just looked at all my notes, I think pretty much fundamentally if we do claim construction now and we hold the rest for another day I think that I don't need to address most of this, but the reality is when you take everything counsel said none of it really went to claim construction.

THE COURT: Okay. And if I have any follow-up questions when I'm trying to, you know, synthesize what I'm being told I won't hesitate to ask.

MS. BEN-AMI: Because I appreciate that because when you look at the claims, and you look at Apotex's claim construction in that little chart we put up to you with each claim BMS construction, Apotex construction, you'll see it is not really claim construction. And I think that if we follow the law we should -- we really don't need to do most of that -- most of what they addressed.

So, I think I'll just leave it at that. I pointed out the important part of the spec, and I think that that would be helpful to the Court.

THE COURT: Thank you.

MS. BEN-AMI: So I can just speed things up and go on to the next item --

THE COURT: Please do.

MS. BEN-AMI: -- which would be 127, please. This is the next claimed term, which is about differential scanning calorimetry. I cannot say that. Calorimetry thermogram -- I have done this, but I can't say it -- but thermogravimetric analysis in accordance with Figure 2. And Your Honor has the patent, and Your Honor can look and see that there is a Figure 2.

THE COURT: So, we are now in Claim 6. Excuse me. I misspoke, Claim 12.

MS. BEN-AMI: It is Claim 2. I'm looking at Claim 2.

THE COURT: Yes. That's 2. Yes.

MS. BEN-AMI: So we have to look at --

THE COURT: Claim 2.

MS. BEN-AMI: And, so, when we look at Claim 2, again, we're talking claim construction. What needs to be construed? It says it is characterized by differential scanning calorimetry thermogram, and the TGA analysis is substantially in accordance with that as shown in Figure 2. Well, you have Figure 2.

And, so, if we go to 129 we really are just saying here someone has to look at the figure and see whether they're substantially in accordance. There are not a lot of words in this claim that need construction. No one argues about what DSC is. Nobody argues about what TGA is. If you look at Apotex's construction in the box -- we can go through it together. They say, "must match both these tests."

Now, the claim says, "substantially in accordance." So, they're asking you to rewrite the claim to change the words "substantially in accordance" to "being identical." That's, in our view, an error as a matter of law. The claim says, "substantially in accordance." It doesn't say, "must match, must be identical." It is "substantially in accordance."

Then they add "and further do so in such a way so as to uniquely identify the referenced," and then it quotes "crystalline monohydrate," et cetera. That's not what the

claim says. The claim says, "crystalline monohydrate," et cetera, all right, and it goes through -- it is not an unknown, as we have discussed before. And it simply says that it is the compound of Claim 1. We don't need any additional construction for that part, "which is characterized by these tests substantially in accordance with Figure 2." That's all it says. So, I don't see this need for all these other Apotex suggested words.

Apotex is really asking you to rewrite the claim. "Substantially in accordance" is not "identical" or "must match." It is "substantially in accordance." That's a well-accepted concept. It doesn't say it must do so to uniquely identify. It just says it has to be the crystal monohydrate, it has to have what's in Claim 1, and then it has to have these additional features. And then they argue this concept of indefiniteness because -- for the DSC because the techniques are not -- are not disclosed in the specifications.

THE COURT: Disclosed. What column is Figure 2 in?

MS. BEN-AMI: Figure 2 is right up front.

THE COURT: That would be too easy.

MS. BEN-AMI: It is not in a column. It is Sheet 2 of 7. I think we have a slide of it. We can bring that up. Oh, it is over here. That is small, but you can look at that. And if I can have Slide 136.

So, we have a Slide 136, which labels which is the TGA

and which is the DSC. And you can see --

THE COURT: What slide of yours?

MS. BEN-AMI: 136. So, we have labeled -- so there you can see where the peaks are, and that's what the claim says.

THE COURT: You turned the peaks upside down in Figure 2; the patent holder did.

MS. BEN-AMI: Yes.

THE COURT: That's fine.

MS. BEN-AMI: And they actually say that in the specification, I believe.

THE COURT: Yes.

MS. BEN-AMI: So there's certainly an explanation in the patent. And I think that we pointed out to you -- I'll show you Slide 140 -- I think it is in our brief -- but to the extent that Apotex said, Well, for DSC they didn't go ahead and explain the conditions, and, therefore, it is indefinite, putting aside that that really should be for another day if you look at Column 43 on the patent, Column 43. We were on Column 44 a minute ago. It lays out how these tests were done.

THE COURT: Okay.

MS. BEN-AMI: It gives you the conditions, the open pan, the closed pan, the things that they say are not there. So, when we consider that, that argument really doesn't have

much weight to it at all.

But in any event, I'll try to see what else we should talk about for these two.

THE COURT: Well, don't belabor it.

MS. BEN-AMI: No, I'm going through to see if there's anything else on the subsidiary claims that we need, Your Honor. I think it probably is best if I go through the DSC claim issues.

If we look at Slide 146 -- let's go to 145. That's Claim 9 and Claim 12. And there you'll see it is the compound where the DSC has a broad peak at approximately 95 Celsius -- between approximately 95 at 13, which corresponds to the loss of one water of hydration on the TGA. And, so, what you see is it is, basically, describing the picture, Figure 2. But there's not a lot of claim construction that needs to go on there.

And I think the other claims -- on 148 it says, "a broad peak between approximately" -- that I do remember. That is 95 and 130 C. There was -- the "°" was missing, so it is 95 degrees Celsius to 130 degrees Celsius, but it says "approximately," so it doesn't mean exactly, it means approximately. Again, these are not difficult concepts, and when you look at the spec there's just no real issue here.

And the same for Claim 11. Again, you can't read "approximately" out of the claim. And that's what I have for

the DSC parts of these claims. I think, basically, the words say what they say, and they really don't need any construction, other than the plain meaning.

Thank you.

MS. MAZZOCHI: Just as a preliminary point I think that one of the reasons why we're talking a bit more about the science is because we keep seeing these vague terms such as "substantially" and "approximately," and there really isn't a way to glean what the boundaries are of the claims when they make use of these vague terms. And I think that when you look at the Federal Circuit case law starting with Seattle Box on forward is there's a recognition that patentees can use these terms of degree, which are recognized as being inherently indefinite and vague, but they need to send some clear signals to the person of ordinary skill in the art exactly what those types of degrees are meant to convey. And that's where this patent specification really does fall down on the job, as well as their claims. And that's the reason why we have been focusing on giving the Court illustrations of how "substantially" or "approximately," how it, basically, fails to convey exactly what -- what the metes and bounds of the claims really are.

And just because I didn't get a chance to respond to it, I would want to note that Column 48, Lines 7 to 28, has some unit cell dimensions, same geometry, similar density for

an anhydrate single crystal unit cell. Are they going to say it is approximately the same? Or are they going to say it is something different? So, you know, we're using these as illustrations for why the claims on their face really aren't as precise as counsel asserts that they are.

Now, when it comes to the, you know, the -- you know, so when it comes, for example, to "substantially" whether we're talking about the X-ray, the DSC, the TGA -- you know, for the X-ray, counsel admits lots of polymorph sheer peaks. They don't want peak intensity to matter. But she acknowledges that these don't have the -- these different polymorphs don't have the same pattern. So, then where do we draw the line on "substantially?" They don't say.

For the DSC traces, you know, "the DSC characterized by a differential scale and calorimetry thermogram" --

THE COURT: Slow down.

MS. MAZZOCHI: Sure. "Differential scanning calorimetry thermogram and a thermogravimetric analysis substantially in accordance with that shown in Figure 2."

Okay. Well, when we go to Figure 2 it actually -- and, actually, it is probably easiest, Your Honor, to read if you take a look at Figure 2 in the '725 Patent itself. It does tell you the instrument for at least one thing that they placed here in Figure 2, but it doesn't tell you, for example, that this pattern was taken with a certain type of sample pan.

And their own expert admitted that depending on the nature of the sample pan that you have it is going to change the results.

THE COURT: Well, what about this open pan that is in Column 44 or 43?

MS. MAZZOCHI: Yeah, they mention that they have done the test using the open pan. They don't say and that result is presented in Figure 2, you know. I mean, quite frankly, to me what they're, basically, trying to say is it is perfectly fine for them to import some of these descriptions in the specification into the claims. Well, if they're going to start importing one, then where do you want to stop on that score? But it certainly doesn't say this is the only method to evaluate these, and this is what gets us directly into the case -- the indefiniteness case that we cited in our briefing. And I believe that was Honeywell versus the ITC, 341 F.3d 1332. In that case there was no question that there was a DSC test that was involved. There was no question that people in the art knew that there were different methods that could be used, but there was a crucial step where, depending on how that step was performed, you could get a variety of outcomes, some of which were infringing, some of which were not infringing. That's why the Federal Circuit said that's a crucial thing that you needed to have, basically, made clear.

So, here we're in a similar situation. When you're

dealing with pharmaceutical polymorphs, and you have got the DSC in an open pan, that open pan essentially, as you heat the crystal, it makes it easier for water to escape. So, you get one type of energy absorption within that sample. When you're in a closed pan situation that changes the thermodynamics. You don't have the water escaping as easily, so that changes how things work. I mean, it is the equivalent of if you want to try to --

THE COURT: I know, I know. Let it simmer covered or uncovered makes a difference.

MS. MAZZOCHI: Exactly. You know, so, here they are -- our basic point is that they haven't defined which one it is, and they certainly had the ability to do that and incorporate that in the claims. They certainly in Claim 1 made sure that they were talking about copper K-alpha radiation, and they made sure they were making a description of a temperature. But they didn't do that here.

Similarly -- another problem with saying we want to produce data that looks like Figure 2 in the '725 Patent is that you can't take the same sample and subject it to a DSC test, followed up by a TGA test because -- and somehow it would say it is a monohydrate. When you run -- if you were to say, Let's take the monohydrate, subject it to -- even if we say it is the open pan conditions that produce that Figure 2. After you've gone through this first pass where you see the

endotherm -- and you're right; it typically isn't put that way on patterns -- so when you see the endotherm going down to 125.27 degrees C in Figure 2 that's a process that's essentially destroying the monohydrate crystal.

THE COURT: So, you're saying it is destructive testing for that particular sample.

MS. MAZZOCHI: It is destructive testing for that particular sample. So, if you do it on the first pass you've essentially destroyed the monohydrate crystal by the time you're at, you know, 200, 250 degrees, and I believe counsel's own slide indicated that what you see there then at the endotherm at 286.73 degrees, that is the melting point of a desolvated anhydrate, so somehow in the pan it is recrystallized, and now that's a melting point for an anhydrate peak.

All right. So, let's say you even do that test, you're going to take the same sample, and you're going to subject it to the TGA. Well, you have already driven off the water, so you're never going to get a TGA trace on top that -- I'm sorry, a TGA trace that looks like the one that's on top in Figure 2 because if you have essentially melted and you recrystallized back out this anhydrate crystal it doesn't have any water to lose. So, on its face, even if you accept their open pan representation and read the claim literally it can't work because you've destroyed the sample. So, you can't have

that --

THE COURT: Well, look, I have this little vial here, and I'm going to take my eyedropper, and I'm going to reduce -- I'm going to remove a representative sample from my vial, put it through Test Number 1. I go back to the same vial, pull up a second sample from the same vial, put it through Test Number 2. What's wrong with that?

MS. MAZZOCHI: Well --

THE COURT: I shook the vial.

MS. MAZZOCHI: Sure. And I guess the problem is that when you look at Claim 2, the compound of Claim 1, which is characterized by DSC thermogram and a TGA analysis substantially in accordance with that, you know, so -- you know, they're not saying a pharmaceutical sample, which when tested, you know, gives you this result or gives you this result. It is not clear from their claims that you can actually take those two separate samples and make the assumption that you do have the underlying representative samples and that they're both characterizing that same compound of Claim 1 as they used it in Claim 2. You know, so then -- but, I mean, ultimately, you know, if they want to do that that's going to be their burden of proof, but, you know, in reality with both of these being destructive tests, to do as Your Honor said then the question becomes how do they prove that the two samples that they took, even if they're

representative samples, are, in fact, sufficiently identical to one another that that can support the underlying claims.

And, again, I agree that that would be an issue at trial, but when it comes to the claim construction issue -- you know, our whole point is, again, that what does it mean then to say you've got a sample that's "substantially in accordance" and then, here again, if you know you're going to have variation based on the sample, you know you're going to get different results based on whether it is the first run or if you take the melted anhydrate, let that solidify again and run it through, you know you're going to get a different trace, you know, and then, here again, where do the boundaries lie? You know, where do the peaks start and stop? Where does the endotherm change? What if you've only got a little blip and not something that's got the heat flow measured in Figure 2? When do you fall outside the scope of "substantially the same?" And plaintiffs really haven't given the Court any type of objective standard that can be applied here, and that's why we say that it is indefinite.

Getting to -- and this actually, you know --

THE COURT: And I guess we are familiar with patent case law that says that if the judge just has to throw up their hands and say, No way can I interpret, for Markman purposes, this particular claim limitation, then indefiniteness has been determined at the Markman stage.

MS. MAZZOCHI: Right. That can be done at the Markman stage.

I think if we jump to our Slide Number 43 when it comes to this broad peak issue -- actually, probably the best illustration -- let's actually jump to Slide Number 50. Because, you know, one of the bases of our indefiniteness problems with broad peak in terms of why it can't be really construed here is that their own expert admitted that "broad peak" is a relative term, and that it requires a scale. So, he said, Well, a particular peak, a primary state could be sharp or it could be broad depending on the scale. So, you really need a scale to assign relative breadth of the peak. That scale is missing from the claims. They haven't -- you know, plaintiffs here have not taken the position that there's a way in which the person of ordinary skill in the art could decide on a scale.

THE COURT: You mean one inch equals ten miles they don't have?

MS. MAZZOCHI: Sure. No. Or, you know, the DSC trays should be plotted from location A to B. You know, these are the parameters of the x-axis. These are the parameters of the y-axis. And if we take a look at our Slide Number 51 I just wanted to show Your Honor the reason why this is important is because if you look, for example, at scaling option number one, here we have a range from 100 to 150. Then

on the y-axis we go from minus 4 to minus 6. But if we look at scaling option number two, this is the identical input data, but if you change the scale of the "y," is that even still considered to be a peak? If you look at scaling option number three, where you've narrowed -- I'm sorry, we have expanded the x-axis and then narrowed the trace, is that a sharp peak or is that a broad peak? And then scaling option four, basically, says here's what happens when you change both the x and the y-axis.

So, you know, with just the same type of data, you know, this, basically, illustrates, as their own expert Dr. Atwood testified, the scale really does matter. It is missing, so it is indefinite as to what a broad peak actually is.

And then just as a few further notes, I've got the slides --

THE COURT: But in general, "broad" means the two lowest points of the peak, the distance between those two points in terms of breadth, whereas height would be how far up a given scale the peak rises. "Broad" indicates horizontal width.

MS. MAZZOCHI: Yeah, I think in the context of DSC traces, you know -- and, actually, if we can jump back to Figure Number 2, what they did in Figure 2, you know -- here, if we start on the -- if we start on the left-hand side in

around 50, we see a tick mark there. You know, now is that where they're trying to measure the base of the peak? Or are they trying to measure the breadth of the peak if we start at 100? Kind of drawn this line in? Not clear. Is one broad, the other sharper? If you assume this -- you know, this particular kind of scale? You know, then over here on the right they've got another tick mark that's below 150. But, you know, again, even if you want to say you've measured a particular distance on this x-axis as we just showed in our Slide Number 51 how you scale the y-axis really matters as to whether something looks sharp -- sharp or small. You know, I mean, I might look like a sharp peak if I'm standing next to my toddler. I would probably look like a very short peak if I were standing next to the Sears Tower. So, you know, I think that both the x and the y-axis need to be accounted for when you're talking about matters of scale, and in the claims they didn't do it.

THE COURT: Figure 2 seems to go from 0 to 350 horizontally and from 60 to 110 -- or minus 10 to 0 vertically.

MS. MAZZOCHI: Right. In the context of Figure 2.

THE COURT: Right.

MS. MAZZOCHI: Right. But the broad peak language is not associated with Figure 2 in the context of the claims. The broad peak language appears in -- I believe it is Claim 9

that says, "the compound of Claim 3, the compound being further characterized by a differential scanning calorimetry, having a broad peak between approximately 95 degrees C" -- and this is the 13 degrees C, which plaintiff's counsel wrote as 130 degrees C.

Then in Claim 12 they just say, "crystalline monohydrate of the compound of formula (IV)." They give the structure, "which is characterized by a differential scanning calorimetry having a broad peak between approximately 95 degrees and 130 degrees C."

THE COURT: And in 9 we know there's a typo there. So, that range, 95 to 130 degrees C is identical in Claims 9 and 12.

MS. MAZZOCHI: Right. If we rewrite in Claim 9 13 degrees C is 130 degrees C. I think that's why both sides have treated them -- that claim element together.

THE COURT: Yes. Well, they have a horizontal scale, I think, that shows you where the 95 to the 130 is, right?

MS. MAZZOCHI: Well, they say that the broad --

THE COURT: When you say "x" and "y" -- you like to call them "x" and "y." I like for the record to say "horizontal" and "vertical."

MS. MAZZOCHI: Sure. Sure. Well, there's no doubt that they're saying that the broad peak has to make an appearance with what they say between approximately 95 degrees

C and 130 degrees C as they wrote it in Claim 12. But if you -- I mean, again, even if you were to just plot the region of 95 degrees C to 130 degrees C, depending on what your y-axis is -- I'm sorry your vertical axis units are, again, maybe it looks like nothing.

THE COURT: That's fine. I get it.

MS. MAZZOCHI: So then -- then when it comes to -- since we're talking about some of the melting issues where in the Claim 11 where it talks about "the differential scanning calorimetry further has a peak at approximately 287 degrees C" --

THE COURT: Yes. Now, Miss Ben-Ami, did you cover that yet?

MS. BEN-AMI: I don't think I mentioned it specifically, Your Honor, but to be honest with you, I think that these issues are all the same pretty much, and, so, I think it is fair game.

THE COURT: Go ahead then, Ms. Mazzochi.

MS. MAZZOCHI: My only point is that, you know, when you read Claim 11 it talks about the compound of Claim 9 where the differential scanning calorimetry further has a peak at approximately 287 degrees C. Well, they have already -- plaintiffs have already acknowledged in their own slides that this -- that in Figure 2 what's appearing at 286 and change, in terms of peak position -- this is in their Slide 136 --

they say "peak at approximately 287 degrees C is the melt of the dehydrated form of the compound of formula (IV)."

So, again, we would just note that since they have acknowledged that this -- that this particular peak trace is associated with the anhydrate -- or an anhydrate version -- that's a further reason why the compound of Claim 9, if it was written to be equal to crystalline monohydrate, it would be saying here's a monohydrate that has a peak at 287, but they have acknowledged that the monohydrate doesn't have that peak there. It is an anhydrate peak.

And then, you know -- then I think the only other thing -- and I don't need to go through it, Your Honor; I think it is fairly self-explanatory from our slides -- but, once again, just looking at a DSC trace it doesn't tell you a particular crystal form, so it is not as though you can say a monohydrate will produce an endotherm in this location or an exotherm in that location. You truly need to have some type of a reference standard for comparison.

So, since -- so even if we accept that Figure 2 is their reference standard for comparison that just gets back down to the same original point, which is that they still don't specify in the specification how much deviation is permissible before you can say you've got the type of monohydrate that they intended to claim or you may even have a different monohydrate or a different polymorph all together.

THE COURT: Going back to Claim 12 language --

MS. MAZZOCHI: Uh-huh, yes.

THE COURT: "Broad peak between" -- oh, wait a minute. I'm getting mixed up.

In Figure 2 you just pointed out the 287-degree peak, which, of course, is cited in Claim 11 as a 287-degree peak. And you say that "Bristol acknowledges that's where the monohydrate loses its water and becomes an anhydrate." A-N-H-Y-D-R-Y-A-T-E.

MS. MAZZOCHI: Yes.

THE COURT: Whereas the earlier peak -- whereas the earlier peak between 95 and 130, according to Claim 12 -- I hope I'm not mixing apples and oranges by referring to 11 -- Claim 11 and Claim 12 -- but the earlier peak there between 95 and 130 degrees, according to Claim 12, quote, "corresponds to the loss of one water," unquote.

So, some of the water is coming out earlier in the test, but all of the water is out by the melting point at 287.

MS. MAZZOCHI: I think I follow you. Right.

So, if we follow how plaintiffs are characterizing Figure 2 somewhere below 100 degrees C the monohydrate, they say, starts to give up its water. In theory, when you get to the maximum point of the endotherm, which is the 125.27 degrees C in Figure 2, in theory, that would be the crystal -- the crystalline material you started with has gone

through some type of phase transition, such that it's giving off -- I'm sorry, I always have to try to keep straight the endo versus exo, but, basically, let's just say its heat characteristics are changing, such that it is going from one solid state phase to a different solid state phase.

So, now there's -- it is a question if you look on Figure 2 you see that 180.50-degree tick mark?

THE COURT: Right.

MS. MAZZOCHI: All right. Is that a broad peak? Is it not? You know, that's actually -- it looks like if it is anything, it is an exotherm. Their expert Dr. Atwood said, Well, I think it is just something in the sample pan that's leading to this fluctuation. But there's a possibility that you could -- if it is not due to the single pan then that could be indicative of another phase change.

THE COURT: To the sample pan? If it is not due to the single pan or not due to the sample pan? What did you say?

MS. MAZZOCHI: I'm sorry. Their expert Dr. Atwood took the position that that 180.50 degrees C tick mark that, you know, that kind of --

THE COURT: Yes.

MS. MAZZOCHI: -- deviation from the baseline there, he said that he didn't think that represented some kind of change in the sample being tested. He thought it had

something to do with the sample pan itself experiencing some kind of fluctuation or maybe experimental error, who knows? But I think if I -- but then -- so then by the time we have gotten to temperature 200, 250, nothing much seems to be happening with the sample, but then when we have this endotherm going down that has in Figure 2 the 296.73 degrees, so by the time we're over here (indicating), this is the material that the plaintiffs said in their Slide Number 136 they called that "a peak at approximately 287 degrees C," and they called it "the melt of the dehydrated" -- no water, so it has been fully dried out, so it is an anhydrate -- "form of the compound of formula (IV)."

THE COURT: Okay.

MS. MAZZOCHI: So, now I think the point to be made, though, is that here again, you can't -- if you had an unknown sample you can't look at this within the region of, say, 50 to 150 and assume that you've just got water coming off. If you had, for example, a solvate -- it could be ethanol or butanol, if we use the examples that are in the patent.

Similarly, in the TGA, the TGA it tells you a weight loss, but it doesn't differentiate between the type of molecule that is being lost. So, if, for example, you have -- whether you have water lost, or ethanol lost, or butanol lost all the TGA test tells you is this is the amount of weight the sample has lost as I heat it up. It doesn't tell you and the

material lost was either water or butanol, et cetera.

Now, you know, I think that the argument the plaintiffs are going to try -- plaintiff is going to try to make is they're going to say, Well -- again, using your representative sample example -- they'll say, Well, if we take one sample and we put it in the DSC and another sample, and we put it in the TGA, and if we know in advance that it is already a monohydrate sample and nothing else, then we'll assume that it is water coming off. That's fine.

But when it comes to the unknown sample -- and, yes, the Apotex sample is considered to be an unknown sample. Under USP parlance, anything that's not a reference standard is an unknown sample -- so if we have the Apotex sample or any other, you know, generic, API or butanol solvate, et cetera, that information in Figure 2 is not necessarily enough to allow you to say, I can rule out whether it is or isn't water, et cetera. So, I mean -- so that's one of the inherent limitations of DSC and TGA is that, you know, yes, they do give you some information, but they don't necessarily tell you what a solvent is, where it is bound. You know, they don't tell you, for example, was it bound to Dasatinib? Is it just sitting there? In a TGA test, for example, like if you were to take a sponge and put it in the TGA test, and you just got water that had been absorbed into the sponge flying up into the atmosphere it is going to record a loss of weight, but it

doesn't mean that you actually had a hydrated bathtub sponge. But getting into the TGA, and I think plaintiffs are going to want to talk more about that first, so I'll cede the floor to them.

THE COURT: Thank you.

MS. BEN-AMI: So, Your Honor, I just want to say a few points about DSC and TGA together because I think if the whole thing were to come back to claim construction, the issues seem to be the same. You look at the claims as they're understood by a person skilled in the art, the ordinary meaning, and you're absolutely correct, a person of ordinary skill in the art understands that when you're going to do these tests you're going to take the sample in the vial, and you're going to take part out and you're going to do one test, and that's how it is done in college chemistry class. That's how it is done everywhere. You take part, you put it in, you do one test. You take part, you do it, and do another test. That's how it is understood.

So, we need to construe the claims as those of ordinary skill can understand it, not to give an absurd result. That is a doctrine of patent law.

And then we are to look at the specification to give us guidance. And if we look at Slide 138 -- this is the specification. And it is Column 45. So, we don't have to guess or make things absurd. The person skilled in the art

understands how to do these tests. And to the extent one needs more understanding, the patent written description has told you. And it says right there, "The monohydrate of the compound of formula (IV) is represented by the DSC as shown in Figure 2. The DSC is characterized by a broad peak between 95 degrees and 130 degrees Celsius." That tells you you're looking at Figure 2 and you're looking at the scale of Figure 2, and, you know, when you look at a claim you say, Where is the support for the claim? Right? You have to have written description for a claim. And, interestingly enough, here are the same numbers. They tell you look at Figure 2. So, it all ties together. It is all very clear. It says, "This peak is broad and variable and corresponds to the loss of one water of hydration as seen in the TGA graph." There's not much to interpret here. It tells you what it -- it says what it says.

And the DSC also has a characteristic peak at approximately 287 C, which corresponds to the melt of the dehydrated form of the compound of formula (IV). So it is pretty clear. You take the crystalline monohydrate, and it says that -- I think I showed you before where it talked about the crystalline monohydrate and the DSC -- I won't go back through that -- and it says you take that, you do this DSC testing. There's a change between 95 and 130, that broad peak, right? And it says, "approximately" because it might change a little bit, but you see that broad peak on this scale

of Figure 2, and that's corresponding to a loss of the water molecule, and now you further test it. Every chemical has a melting point test. I mean, it is just standard. And then you see that -- I think it is 287. These are standard chemical tests.

So, while we talk about, wow, this is so indefinite or this is so vague, it is not vague to someone skilled in the art because they do these tests, and they understand these tests, and they know what a broad peak is, specifically since it is shown in Figure 2. And they know what a sharp peak is. And they know what 287 degrees Celsius is. And they know what the scale is.

And, so, I would ask Your Honor to just consider the specification of the patent in construing the claims as consistent with the law, and I think there should not be an issue on these claims.

THE COURT: I understand your argument.

MS. BEN-AMI: So I think there was --

THE COURT: "While we have weight loss of 3.48 percent," which is where?

MS. BEN-AMI: So we looked at Figure 2, and it is shown on Figure 2. I think it is easiest --

THE COURT: I see it right there.

MS. BEN-AMI: Right.

THE COURT: It is the text at the top of the chart.

3.48 percent weight loss from 150 degrees to 175 degrees Celsius.

MS. BEN-AMI: I think it says "50 to 175."

THE COURT: Yes, I misspoke.

MS. BEN-AMI: That's right. It is Figure 2. And if we look at 163 --

THE COURT: Slide 163.

MS. BEN-AMI: Right. Slide 163, I'm sorry. Basically, our claim construction is the words speak for themselves, and it says, you know, "and subject to the normal experimental error."

THE COURT: What about if you did a test not using an open pan, how would this whole testing data change?

MS. BEN-AMI: Well, we don't know whether it would change or not. There's no evidence that says it would or would not change, but what we do know is if you look at the specification it tells you all the tests were done with the open pan, because if I can get my patent --

THE COURT: And it is not a process patent, so you don't have to be limited to an open pan, but this is just by way of saying what this substance does when tested that way.

MS. BEN-AMI: I think that's right. I think that's the difference is you can say I run a test to show that there's infringement, right? That doesn't mean that the alleged infringer had to run the same test. This is a way of

characterizing the monohydrate compound. And, so, I can say, I want to run a nuclear magnetic resonance test. That doesn't mean they had to do it. If I claimed a nuclear magnetic resonance test, then I could do it. So, here in this patent it says in Column 43, "The DSC instrument used to test the crystalline forms" -- and it gives you the instrument. And then it lays out the conditions. And then on Column 45, Line 15 it says, "The monohydrate of the compound in formula (IV) is represented by the DSC as shown in Figure 2."

So, when you put those two columns together Figure 2 had to be done under those conditions because it says these are the conditions for the tests. The fact they're on two different columns it really shouldn't make any difference. This is where they're doing their methodology.

So, again, we don't have to guess. The patent specification tells you exactly what you're supposed to do, how it is done, and since the claims talk about look at Figure 2, I think that the specification makes perfect sense and the claim makes perfect sense.

On the issue of the water loss, I think that Apotex's argument is --

THE COURT: They say, "A compound does not lose weight."

MS. BEN-AMI: Okay. So, this is really the -- when they're talking about the compound, they're talking about the

crystalline monohydrate or they're now saying that's only the Dasatinib without the water, right? Now, all these claims with melting temperatures -- and when you read the spec it is clear it is the crystalline monohydrate. Claim 1 is to the crystalline monohydrate of the formula. And when you lose the water, you lose the weight.

THE COURT: And you lose the monohydrate.

MS. BEN-AMI: It no longer is the monohydrate. I can take that anhydrate form now -- it is destructive testing. I can run another test, and I can break all the bonds. Remember all those lines, all those bonds? And I can figure out how many carbons there are, how many nitrogens there are, and how many oxygens there are. That's a way of characterizing the crystalline monohydrate because I run different tests that give me different pieces of information. So, that doesn't mean --

THE COURT: So, you can deconstruct it --

MS. BEN-AMI: Right.

THE COURT: -- just as you want to show its various properties.

MS. BEN-AMI: Right. Physiochemical characteristics. And, so, that doesn't mean we're not testing the monohydrate. We test the monohydrate by destroying the monohydrate, in effect, to see its different chemical -- physical chemical properties. And that's how it is being characterized. And

that's elementary chemistry. That is college chemistry.

So, that's all I have for that. And I think counsel already did that part.

THE COURT: We may be done.

MS. BEN-AMI: There's only one other part that I saw, and I don't think we need to go into great detail to it. It was -- there's the term, "a process for preparing the compound of Claim 3."

THE COURT: Is that something to be construed?

MS. BEN-AMI: Apotex makes an argument about it that it should be construed to require that the process must -- the entire process must be done in the United States, and it cites, Your Honor, some case law, and the only thing I can say about that, Your Honor, is the case law, some of it was construed before the enactment of the statute 35 U.S.C. 271(g), which is a process outside the United States, you bring the product into the United States, that's infringement of the process.

THE COURT: What year was that law? It is not last year's law?

MS. BEN-AMI: No. It is old. It is old, but the case they cite -- I think it is the Eli Lilly case. It is older. It has been around since the '90s, maybe earlier. And they cite to a couple of other cases where you'll see the Courts don't apply 271(g) because of the particular facts of

that case. So, again, the name of the game is the claim. The claim says "a process." It doesn't say where. That's for a later date. That's all I have.

THE COURT: Thank you.

MS. MAZZOCHI: Just a couple of quick responses, Your Honor. On the DSC, again, Claims 9, 11, and 12 do not, quite unlike the specification in the Slide 138 that counsel pulled up, say, the monohydrate of the compound of formula (IV). The claims just say, "the compound."

Similarly, Claim 10, to the extent it talks about weight loss of 3.48 percent, it just says, "The compound of Claim 9 has a weight loss of 3.48 percent." That weight loss could be due to loss of a solvent like ethanol. It could be due to loss of a different solvent, such as butanol. It could, also, result from adsorbed water that is not in the unit cell of a crystal, and it can, also -- if you're talking particularly about a formulated product to the extent plaintiffs want to argue that their claims cover a formulated product -- could be coming from other excipients associated with a test sample.

So, you know, again, that's why the language of Claim 10 we think it creates some improper dependency problems. And, again, it is not specific in -- and really capable of characterizing a monohydrate as this language is written.

When it comes to -- and some of the admissions on this

from their own expert are set forth in the new slide deck that we gave here.

As for Claim 6, you know, we can't -- we're somewhat baffled why the plaintiffs don't want to agree that to the extent Claim 6 covers any type of process it has to be a process performed in the United States. U.S. patents do not have an extraterritorial affect. To the extent the plaintiffs have invoked 271(g), I would just note this is not a 271(g) case. They haven't pled it. It is a 271(e) case under Hatch-Waxman. So, it seems to me they may be trying to avoid the construction to get at an issue that otherwise might not be actionable under Hatch-Waxman.

THE COURT: You spoke in code literally, and this is an ANDA case, and the question is whether your stuff is going to infringe their patent when you try to put your material on the market.

MS. MAZZOCHI: Right.

THE COURT: And, so, why do we worry about a process claim anyway right now?

MS. MAZZOCHI: I have no idea why they asserted a process claim because Apotex does not make any product in the United States. But they have asserted it. We don't know, you know -- because, again, this is a Hatch-Waxman case. Really, our Paragraph 4 certification is if the product is approved by FDA, you know, will that product, you know, when commercially

marketed, et cetera, et cetera. I mean, that's the fundamental Hatch-Waxman standard. It is -- you know, that's 271(e) of the statute, which creates the Hatch-Waxman liability. When it comes to process claims they typically aren't asserted in Hatch-Waxman cases, particularly when you have foreign manufacturers.

THE COURT: Can you address the other point, though, to the effect that under United States patent law a process claim can be infringed by a process that's carried out beyond our borders if the result of the process is sought to be introduced within our borders.

MS. MAZZOCHI: Yeah. I don't know that that's necessarily a correct reading of 271(g). I would have to actually pull up the statutory language itself because I think there's also some caveats that if you make changes to the product before it crosses the border you may not have the importation issue. Here I don't think there's any question that the raw material -- which is what this patent is directed to -- it is going to get mixed with excipients and everything else. So, you know -- and that's why, again, to me these 271(a) cases, unless you've got -- I mean, usually to the extent you -- sorry, 271(e)cases.

Usually to the extent you see process claims being asserted against generic manufacturers it is for the generic manufacturers who actually make and sell the raw material and

distribute it through the U.S. so they've got a sales agent in the U.S. that will, you know, sell it elsewhere, or maybe they're actually making it here and are using it here during the formulation process. But for the Apotex material, none of our -- none of our, quote/unquote, "process conditions" are ever going to take place in the United States. So, you know, I don't necessarily know that 271(g) even would be applicable here if the only thing we're importing are the finished products. But even if it were, 271(g) has not been pled as a theory for recovery in this case.

THE COURT: At any rate, the claim language in Claims 6 and 7 of this patent, quote, "a process for preparing the compound of Claim 3," unquote, I don't know why it would have to be construed at this point in terms of geographic location of that process.

MS. MAZZOCHI: Well, Your Honor, I think that to the extent -- you know, to me because this is a United States patent I think that by definition any process that's being discussed has to be carried out in the United States, and this isn't a situation where, you know, maybe the heating takes place in one country, and dissolving the compound takes place in another part of the country or within this country. You know, I think that when you're looking at Claim 6 it is talking about a particular process. It seems to be a fairly integrated, uniform process, and, you know, again, to the

extent steps are going to be taken, because this is a U.S. patent, we would just ask that it be construed as occurring here in the United States.

THE COURT: I understand.

MS. MAZZOCHI: Thank you, Your Honor.

MS. BEN-AMI: Your Honor, I would like to hand up the Eli Lilly case, a part of it, to clarify this for Your Honor.

THE COURT: This has already been cited, right?

MS. BEN-AMI: Yes. But you asked -- the Eli Lilly case goes through the issue. It says, "prior to the enactment of the 1988 statute." You asked me when the statute was enacted. And then that was the law. But it says, "By enacting the Process Patent Amendments Act, the principal portion of which is S 35 U.S.C. § 271(g), Congress changed the law by making an active infringement to import into the United States or to sell or use within the United States a product which is made by a process patented in the United States if the importation, sale, or use of the product occurs during the term of such process patent." There are two basic caveats. The caveat is where there has been a material change to the product. So you have the process made outside the United States. A product is made, right? Has it been materially changed or is it a minor component of the mixture that comes in?

So here -- that's the law. And in Slide 65 that Apotex

provided, Your Honor, they changed the quote to -- it says, "but had no cause of action," and they changed it to, "but has no cause of action." It is "had." Prior to 1988 you had no cause of action for a process done outside the United States when the product was imported. Post-1988 you do have a cause of action.

And 271(e), the Hatch-Waxman Act statute provides you this technical infringement by filing the ANDA, right? But you still need to prove infringement under 271(a) or 271(g) or one of the other 271s.

THE COURT: Including a process patent.

MS. BEN-AMI: Yes.

THE COURT: Okay.

MS. BEN-AMI: Because that is -- when we think about the concept of Hatch-Waxman we're thinking about this concept that but if you file the ANDA, and then during this time period you're supposed to work out whether this product, when it was sold or processed, is going to be an infringement. And if it is, and the patent is valid, you don't get approval. So, yes, of course, you do it now.

THE COURT: Okay. Fine. Thank you.

MS. BEN-AMI: The only other thing I would point out to Your Honor, because we keep going back to this water issue, is if you look at Claim 9 it is dependent on Claim 3.

THE COURT: I know.

MS. BEN-AMI: So you have Claim 3 is the crystalline monohydrate, et cetera. Then you go to Claim 9. It says, "The compound of Claim 3 where it is further characterized," and where it says, "which corresponds to the loss of one water of hydration." So, that compound must have one water of hydration. That's what the claim says. So, if you take that back, and you go -- so that's the compound of Claim 3. It has that one water of hydration.

THE COURT: I don't want to get into this, but if it only has one water of hydration then doesn't it become an anhydrate at the point between 95 and 130, rather than becoming an anhydrate at the melting point, 287?

MS. BEN-AMI: In theory if 100 percent of the water is out during that time the water is lost, and, so, it is no longer a monohydrate.

THE COURT: Between 95 and 130.

MS. BEN-AMI: Right.

THE COURT: But it is a monohydrate, so once it loses its one water, it is out of water.

MS. BEN-AMI: Yes. However, when we talk about here -- we'll go back to what I said before. You start with a compound. And you do destructive testing to it. And, so, I look at a part of it. I can say part of it -- I'm going to say, When does the water come -- of the monohydrate come off? Then I'm going to say, When does the part melt? Then I'm

going to say, How many carbons are in it? And I'm going to do a different test. How many oxygens are in it? You're still getting all the physical chemical characteristics of the crystalline monohydrate.

THE COURT: Okay. Now, I understand. You have a melted anhydrate by the time you get to 287 --

MS. BEN-AMI: Right.

THE COURT: -- whereas you're pretty much at the anhydrate stage between 95 and 130 when your one and only water comes out.

MS. BEN-AMI: Basically, that's right. So, look at it slightly differently, which is, I'm trying to figure out the physical chemical properties of the monohydrate compound, right?

THE COURT: Physical and chemical?

MS. BEN-AMI: They call it physical chemical, like physical chemistry. Melting temperature is physical chemistry. Phase change, going from a solid to a liquid, a liquid to a gas is a physical chemical property.

THE COURT: Okay.

MS. BEN-AMI: How it absorbs energy is a physical chemical property.

So, I'm going to say, I want to see when I heat it up, for example, how does this crystalline monohydrate change? So I'm saying, Okay, I see this physical chemical change of the

crystalline monohydrate here. I see a later change at 287. They're both characteristics of the crystalline monohydrate. They're both characteristics because you're taking that crystalline monohydrate --

THE COURT: I understand that. I understand that.

MS. BEN-AMI: Okay.

THE COURT: But, basically, essentially when the, quote, "one water" comes out in Claim 9 --

MS. BEN-AMI: Uh-huh.

THE COURT: -- and you have a monohydrate that you're testing, then one water coming out does mean that you're getting to something that isn't a monohydrate through your testing process.

MS. BEN-AMI: By destroying the monohydrate yes, yes.

THE COURT: Right. But the one water that comes out between 95 and 130 is all the water that this substance has to offer you.

MS. BEN-AMI: For each molecule of Dasatinib there's only one water. So if there's 100 percent, you know -- if the experiment is 100 percent perfect in theory, which no experiments are, then you would say all the water was out at that time.

THE COURT: Okay. But some may be a little bit reluctant --

MS. BEN-AMI: But you've got the concept correct that

water is coming off at one temperature. The rest of it is melting at a different temperature. That's, basically, what it is about.

THE COURT: Okay.

MS. BEN-AMI: Thank you, Your Honor. I think we're done.

THE COURT: Because I'm giving your adversary a dirty look.

Go ahead, Ms. Mazzochi, from the table, please.

MS. MAZZOCHI: If there's any other questions that Your Honor wants answered, I'm happy to answer them.

THE COURT: Well, I'll send out -- I'll send out life lines. I need them. Okay?

MS. BEN-AMI: Thank you, Your Honor. We appreciate all your time.

(Proceedings concluded at 12:58 p.m.)